The role of psychological factors in predicting quality of life in patients with head and neck cancer : applying a self-regulatory framework to explore adaptation and outcome

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The role of psychological factors in predicting quality of life in patients with head and neck cancer: Applying a self-regulatory framework to explore adaptation and outcome

Thesis
presented
to the

Institute of Psychiatry

King's College London

University of London

for the degree
of
Doctor of Philosophy

Field of study: Psychology as Applied to Medicine

Submitted by

Carrie Diane Llewellyn

2005

ABSTRACT

This thesis explores the role of psychological factors in predicting quality of life in patients diagnosed and undergoing treatment for head and neck cancer (HNC). A self-regulatory framework was used as reference for guiding the selection of psychological factors related to adaptation and outcome. The main aim of the thesis was to investigate the effects of illness and treatment beliefs on both standardised health related quality of life (HR-QoL) and individualised quality of life (QoL).

The literature review is presented in two parts. The first part provides an overview and critical appraisal of the literature evaluating the impact of HNC and its treatment on HR-QoL. The second part consists of a systematic review assessing psychosocial and behavioural factors associated with HR-QoL in HNC. An additional chapter provides a critical overview of the wider literature reporting psychological factors found to be associated with QoL in cancer in general.

The empirical content of the thesis begins with the results of a qualitative pilot study examining, firstly, the types of expectations patients had prior to treatment and the extent to which patients considered that these expectations had been met post treatment, and secondly, the role of information on the development of expectations.

A prospective questionnaire based study with a sample of eighty-two HNC patients provided data for testing the main hypotheses. Patients completed questionnaires assessing illness and treatment beliefs, mood, coping, optimism and individualised and standardised QoL at three time points. Results based on pre-treatment data indicated that patient's perceptions of their illness and treatment, and style of coping were shown to be determinants of HR-QoL but not individualised QoL.

Finally, a cross-sectional questionnaire based study assessing long-term adaptation was conducted using patients with cancer of the head region, two additional patient samples (patients with cancer of the glottis/ larynx and surgical patients with benign salivary gland conditions) and a matched non-patient sample, for comparisons. The main aim was to assess factors that were associated with long term subjective-well being (i.e. cognitive and emotional adaptation) after treatment.

Results demonstrated that time since treatment had no effect on adaptation in any of the clinical samples. HR-QoL and optimism was found to explain 70% of variation in emotional adaptation (depression scores) in patients with cancer of the head region. Approximately 50% of the variance in cognitive adaptation could be explained by optimism, HR-QoL and treatment type.

The limitations and implications of the studies and literature are discussed.

ACKNOWLEDGEMENTS

I would firstly like to thank my supervisors, Professor John Weinman and Professor Mark McGurk at Guy's Hospital. John, for providing his usual excellent guidance and support, and knowing when to leave me alone and when to rein me in. Mark for his expertise in head and neck cancer and brilliance as a surgeon and for also giving me a large dollop of latitude against his better judgement. Both have been excellent supervisors for three years for very different reasons and I have learned a great deal.

This research would not exist without the enthusiasm and interest from the patients who participated in these studies at a difficult period in their lives. I can only say thank you and acknowledge that many of these individuals have been an inspiration. In addition I would like to acknowledge the assistance provided from the medical and non-medical staff, in particular the consultants who showed an interest in my work and allowed me access to their patients at the following hospitals: Guy's, King's and St Thomas' Hospitals (Andrew Lyons, JP, and the senior registrars); The Royal Sussex County Hospital (Jim Herald, Keith Altman and Mr Weighill); The Royal Marsden Hospital; and University College Hospital (Laurence Newman).

This thesis was supported by a 'prize' PhD stipend awarded by Guy's and St Thomas' Charitable Foundation, for which I am indebted.

I am grateful for informal discussions and support from many colleagues too numerous to list but they know who they are, and my friends and close colleagues Kristina Karamanidou, Suzanne Scott, Florien Vogt and Jodie Main for providing a lot of entertainment during conferences and being supportive over the least three years. A very special thank you goes to my friend and soon to be husband Alec who has had to suffer with patience many hare-brained schemes brought on by PhD inertia over the last three years, and is looking forward to a well earned rest (no chance) after this thesis has been handed in.

Lastly, I would like to thank my immediate family and friends who have been constant and caring, and yes, mum and dad, Tina and Mark, I know it's hard to believe - but I am not a student any more.....

This thesis is dedicated to Peter Mente (1947-2005)

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CHAPTER 1

INTRODUCTION

"How am I? Who knows? Nine months or so after the operation I'm back on an almost entirely liquid diet – the radiotherapy put paid to any solids I was managing ....I'm also in pain for much of the time. I have to sleep upright because with my saliva glands gone I still have mucus problems. I have no real sense of taste and retain a propensity for long coughing jags that keep me out of the cinemas and the theatre. I have a voice, of sorts, and although it is one which causes strangers TO. SPEAK. TO. ME. LIKE. T-H-I-S. as if I were a mentally retarded deaf mute....it means I can join in conversations."

(Diamond, 1998)

1.1 HEAD AND NECK CANCER (HNC)

1.1.1 Definition

'Cancer' is another term for malignant neoplasm. The pathology of malignant neoplasms of the head and neck can be subdivided into 'squamous cell', 'basal cell', 'salivary', 'thyroid', 'odontogenic and bone/cartilage tumours' and 'others'. Most cancers of the head and neck are squamous cell carcinomas (SCC) arising in the mucous membranes of the mouth, pharynx and larynx and are considered alcohol and tobacco related.

Most international databases employ the World Health Organisation's (WHO) International Classification of Diseases coding system, and most data currently available are expressed in the 9th or 10th revisions (ICD-9 or 10). The term 'head and neck cancer' usually refers to the following sites and codes (ICD-10): Malignant neoplasms of the lip (C00); base of tongue (C01); other and unspecified parts of the tongue (C02); gum (C03); floor of mouth (C04); palate (C05); other and unspecified parts of the mouth (C06); parotid gland (C07); other and unspecified major salivary glands (C08); tonsil (C09); oropharynx (C10); nasopharynx (C11); pyriform sinus (C12); hypopharynx (C13); other and ill defined sites of the lip, oral cavity and

pharynx (C14); nasal cavity and middle ear (C30); accessory sinuses (C31) and larynx (C32). Tumours of the skin (unless SCC), eye and brain are normally excluded from the term 'head and neck cancer'. It is important to recognise these site subdivisions as they have distinct management and treatment protocols and differing physical morbidities associated with their diagnosis and treatment.

1.1.2 Epidemiology of head and neck cancer

The incidence of cancer of the mouth and pharynx ranks *sixth* of all cancers in the world and ranks *third* in developing countries (Parkin, Whelan, Ferlay, Raymond, & Young, 1997). Striking differences in incidence rates exist between different geographical (and therefore cultural, ethnic and socio-economic) regions. In developed countries, the number of cases with cancer of the mouth or pharynx is higher than that of cervical cancer. Cancer of the mouth, pharynx and larynx (ICD-10: C00-C14 & C32) is the *fifth* most common anatomical site for cancer in the world, with half a million incident cases of oral and pharyngeal plus laryngeal cancer cases in 1990 (Ferlay, Parkin, & Pisani, 1998; Parkin, Pisani, & Ferlay, 1999). H&N cancer is responsible for 12% of male and 7% of female cancers in the developing world and 7% and 2% respectively, in developed countries (Sankaranarayanan, Masuyer, Swaminathan, Ferlay, & Whelan, 1998). In the United Kingdom, considerably higher incidence rates are reported in Scotland and Northern Ireland (NI) than in England and Wales for both sexes, although the difference is greatest for men. The male European age standardised rates for oral cancer (ICD10 C00-C14, excluding C07/08 & C11) were approximately 13 per 100,000 population in Scotland and NI (4.5 for women) compared to approximately 7 per 100,000 (3.0 for women) in England and Wales (CRC, 2000). Altogether, the figures for H&N cancer represent a substantial disease burden, with high mortality rates of 54% overall: death to registration ratios range from 0.47 to 0.65 according to site (Johnson, 2002).

1.1.3 Aetiological factors

Carcinogenesis in the head and neck is multi-factorial and exhibits considerable inter-individual variation. Excessive alcohol intake and a long history of tobacco use in its many forms, are considered to be the principle risk factors. The risk is strongly enhanced by the synergistic action of tobacco and alcohol together. If the risk for an abstinent individual is 1, the relative risks are approximately 5, 18 and 40 for light drinkers or heavy smokers, light smokers and heavy drinkers, and heavy smokers and heavy drinkers respectively (Rothman & Keller, 1972). This reflects the fact that 90% of patients have a long history of tobacco smoking and alcohol intake. Continued tobacco consumption following treatment for HNC is also recognised to increase the risk of recurrence (Benninger, Gillen, Thieme, Jacobson, & Dragovich, 1994; Rothman et al., 1972; Silverman, Gorsky, & Greenspan, 1983; Stevens, Gardner, Parkin, & Johnson, 1983) or secondary HNC (Moore, 1971; Wynder, Dodo, Bloch, Gantt, & Moore, 1969) and to reduce disease-specific survival (Browman et al., 1993b; Stevens et al., 1983).

Betel-quid chewing with or without the inclusion of tobacco products has also been identified as a major risk factor for oral cancers in Asian populations. In recent years, there has been an enormous increase and availability of betel products for sale in the UK, both as separate ingredients or pre-packaged (Williams, 1995). This has encouraged the perpetuation of these highly carcinogenic practices. Other aetiological factors are thought to include exposure to viruses, such as the human papilloma virus (HPV16 & 18) (Gillison & Shah, 2001; Mineta et al., 1998; Wilczynski, Lin, Xie, & Paz, 1998) and Epstein-Barr Virus (EBV) (D'Costa, Saranath, Sanghvi, & Mehta, 1998; Kobayashi et al., 1999) although these conclusions are still plagued with controversy.

1.1.4 Prognosis

The five year relative survival rate reported by the Surveillance, Epidemiology and End Results (SEER) program of the National Cancer Institute of USA, for oral cavity and and pharyngeal

cancers (1986-1991) was 52.1%; cancer of the larynx was 65.7%, and there has been little difference in survival rates over the last few decades (Carvalho, Nishimoto, Califano, & Kowalski, 2005). For localised lip, salivary gland, paranasal sinus and laryngeal cancers, five year survival exceeded 80%; ranging between 65-79% for localised tongue, mouth and nasopharyngeal cancers. However, five-year survival rates were less than 50% for localised cancers in other H&N sites. The five year relative survival rates reported from 11 countries in the European Cancer Registry based Study of Survival and Care of Cancer Patients (EUROCARE) were as follows: tongue: 39%; oral cavity: 46%; oropharynx: 33%; nasopharynx: 38%; hypopharynx: 19% and larynx: 54% (Berrino, Esteve, & Coleman, 1995). In developing countries, five-year relative survival for the majority of subsites (excluding lip) tends to be less than 35%.

Clinical extent of disease seems to be the most important prognostic factor affecting outcome of treatment. Outcome results for moderately advanced H&N tumours are poor regardless of treatment. Advances in treatment (e.g. adjuvant chemotherapy, modified radiotherapy regimens, as discussed below) have not improved long term survival in the case of advanced HNC (Sankaranarayanan et al., 1998).

1.1.5 Treatment /management strategies

Treating HNC patients for cure involves either surgery, radiotherapy and/or chemotherapy in varying combinations. Each treatment has its on toxicities and adverse late effects which are often intensified when used in combination. Small primary tumours can be eradicated by either surgery or radiotherapy. In cases involving less accessible lesions (e.g. the vocal cords, tonsil and hypopharynx), radical radiotherapy can enable good function and cosmesis to be retained and this is generally the treatment of choice. Salvage surgery may be required in those patients with residual or recurrent disease after radiotherapy (Bloom, 1987).

The high doses of radiotherapy required to gain locoregional control of HNC are associated with an increased risk to normal tissue. Acute skin and mucosal reactions are common during irradiation and generally subside after treatment. Late irradiation-induced changes can lead to fibrosis and may lead to permanent and serious problems with regard to function, comfort and cosmesis. The most frequent effects following treatment with radiotherapy are due to the reduction of saliva following direct or incidental irradiation of the salivary glands. The resulting mouth dryness (Xerostomia) may lead to rapid and severe widespread dental caries (Bloom, 1987), difficulties eating with a decreased or lack of taste and smell, or problems speaking. Brachytherapy (external local dose of radiotherapy, usually as an interstitial iradium implant) has become an optional treatment, especially in the oral cavity and pharynx. This reduces the area of tissue affected by side-effects, but due to the high levels of radiation, may increase the side-effects in the smaller area (Hammerlid, Mercke, Sullivan, & Westin, 1997b). New computer based techniques allow the radiant beam to be adapted to the tumour but the more concentrated dose, especially with concomitant chemotherapy, results in scarring and reduced function.

During the last twenty years, the advances in intra-oral soft tissue reconstruction by revascularised tissue transfer (e.g. from pectoral or forearm donor sites) have lead to more extensive tumour ablation in patients, as even large defects can be repaired in one step procedures. Due to this, current techniques give improved cosmetic results to previous, but still poor functional effects, frequently leading to problems eating, drinking, speaking or even breathing.

In advanced cancers, chemotherapy is being used more frequently in combination with radiotherapy with the goal of organ preservation in the 'neoadjuvant setting' (chemotherapy as a substitute for surgery in treatment of advanced resectable HNC). Loss of many vital functions (such as those highlighted above) can result (Ganz, 1990).

A critical prognostic factor in HNC is spread of disease to regional lymph nodes (Schuller, McGuirt, McCabe, & Young, 1980). The traditional gold standard for regional disease control has been radical resection of all lymph bearing tissues in the neck. This included removal of the spinal accessory nerve (SAN), which leads to patients suffering from 'shoulder syndrome'. This syndrome was characterised by a shoulder droop, weak abduction, restricted movement and a dull ache with pain localised to the shoulder. More conservative modifications to this classic dissection have meant sparing the SAN whilst still controlling disease and decreasing the associated morbidity. Despite this, neck dissection is still responsible for permanent and significant change in shoulder function as well as increased postoperative pain.

1.1.6 A brief overview of psychological sequelae of HNC and treatment

The diagnosis of cancer is frightening for patients and their families. Cancer of the H&N not only poses a threat to life but, in patients who survive, self-image and confidence is challenged through the consequences of the disease itself and the results of treatment.

There is ample evidence that psychological distress is common in HNC patients (Hutton & Williams, 2001). Given the visible deformities caused by the cancer and treatment, studies have been conducted to identify the psychosocial impact. Results have been conflicting. Anxiety has been reported as a frequent general symptom in HNC patients (De Boer, McCormick, Pruyn, Ryckman, & van den Borne, 1999) although the experience of stress associated with HNC has been found to be greatest at diagnosis decreasing as the patient progresses through treatment (Manuel, Roth, Keefe, & Brantley, 1987). Reports of the prevalence of depression in these patients are also inconsistent. However, anxiety and depression have been associated with poor function (Hassanein, Musgrove, & Bradbury, 2001). Due to the cancer and treatment, many patients must discontinue their usual activities or jobs and as a result often become socially isolated. Areas of life that are affected the most by HNC include; communication,

functioning in the family and social and interpersonal relationships (De Boer et al., 1999). The extent of disruption to sexual functioning has not been investigated fully, although it has been suggested that patients with extensive disfigurement report significantly greater reduction in sexuality than patients with minor disfigurement (Gamba et al., 1992).

In the last few decades, interest in the issues, which impact on an individual's life the most, has increased. The term quality of life (QoL) although widely used, is problematic to define, however, many instruments for measuring this concept exist. Measurement of QoL usually refers to *health-related* quality of life (HR-QoL) and typically includes enquiry into patient perceptions of; physical function, symptoms, performance and emotional aspects. Psychological distress or functioning is rarely included within HR-QoL measurement.

1.1.7 The context of the thesis

Head and neck cancer remains a highly physically and psychologically traumatic disease. The basic functions of seeing, swallowing, hearing, smelling, and ultimately of communication depend on each element working together in harmony. The function and appearance of the head and face are critical to an individual's self-image. Although disfigurement and body-image concerns are recognised as critical factors in psychosocial rehabilitation and adjustment after HNC (Clarke, 2001; Dropkin, 1998a; Dropkin, 1999; Lansdown, Rumsey, Bradbury, Carr, & Partridge, 1997), these aspects have not been included in this thesis for a number of reasons. Firstly, the literature detailing the effects of disfigurement in HNC patients is extensive and it would not have been possible to do justice to this specific area by incorporating facets within the current focus of the PhD. In addition, not all patients have to cope with outward disfigurement despite facing functional difficulties, and thirdly, coping with an altered appearance is one factor that could influence adaptation. However, the underlying belief system that patients had developed in response to their illness as a whole and their associations with outcome (adaptation) were of primary interest, rather than focusing on one very specific factor.

Despite recent developments in reconstructive techniques and more sophisticated treatment regimes involving specialist multidisciplinary teams, the survival rate in advanced disease has remained at approximately 50%. Continuing efforts such as conservation and reconstruction procedures, speech therapy and prostheses have been directed towards lessening the impact of the disease and its treatment in terms of disability and functioning. Comprehensive assessment of the impact of head and neck cancer once clinical outcomes such as survival and disease progression have been established, go beyond level of functioning, to include patient wellbeing. The interest in HR-QoL has increased in recent years and much published data exists examining QoL issues in HNC patients. Although exciting developments continue in the area of longitudinal research that report changes in HR-QoL over time, there is a paucity of research examining the patient's subjective judgement of their own QoL in terms of the priorities they have throughout their cancer journey.

Variation in QoL (both between patients and over time) may be due either to differences in functional status (physical disability) or may reflect the underlying belief system the patient has about their illness and treatment, for example, in terms of the likely causes of the disease, its time scale, whether the illness is likely to be chronic, acute or cyclical, its controllability and the perceived consequences. By examining these beliefs, adaptational processes may be revealed, for example cognitive 'shifts' in which a patient's internal standards change over time and with experience.

The primary value of understanding individual variation in QoL is to attempt to minimise the impact and intrusion of HNC to a patient's life. By understanding the relationship between outcomes such as QoL, and potentially modifiable psychological factors, such illness perceptions, patients long-term QoL can perhaps be enhanced by designing appropriate interventions based on theoretical underpinnings.

1.1.8 Outline of Chapters 2 and 3: Literature reviews

The literature reviews are presented in chapters 2 and 3, which were conducted in order to identify gaps in the literature and to provide a basis for formulating specific research questions and hypotheses for the thesis. The first of the literature reviews (chapter 2, part 1) seeks to critically examine the evidence for the impact of head and neck cancer and treatment on outcomes such as HR-QoL and depressive symptoms, and the evidence for socio-demographic, clinical and treatment related factors predictive of HR-QoL in this patient group.

Part two of chapter 2 consists of a systematic review, which was undertaken to assess whether there were any psycho-social or behavioural factors that are associated with HR-QoL in HNC and the extent to which depressive symptoms and HR-QoL are related.

Chapter 3 introduces the theoretical context to the thesis, in terms of Leventhal's self-regulatory model (SRM), which has not been widely applied in the field of HNC previously. This provides a critical overview of the literature evaluating the role of psychological components of the SRM on outcomes such as quality of life and psychological well-being, in a wide variety of illness groups. The role of expectations on perceptions of outcome is also considered. Chapter 3 also contains a brief overview of the concept of 'response-shift' in the context of QoL research, and the current approaches to measuring QoL in terms of conceptual and methodological issues in addition to the clinical implications.

Implications of the literature reviews for the thesis are thus presented afterwards followed by the main aims and key objectives of the current research.

CHAPTER 2.

THE HEALTH RELATED QUALITY OF LIFE (HR-QOL) OF PATIENTS DIAGNOSED WITH HEAD AND NECK CANCER (HNC)

The following chapter has been divided into two parts. The first part of chapter 2 seeks to provide an overview and critical appraisal of the literature assessing the impact of HNC and its treatment on HR-QoL and considers the socio-demographic and clinical factors associated with HR-QoL. The second part of chapter 2, consists of a systematic review examining the extent to which psycho-social and behavioural factors are related to HR-QoL in this patient group.

2.1 PART 1: CRITICAL REVIEW OF THE LITERATURE

Research question: To what extent does HNC and its treatment impact on HR-QoL?

2.1.1 SEARCH TECHNIQUES AND TERMS

2.1.1.1 Databases

The following databases were searched: Medline 1982-present; CancerLit 1985-2002; Embase 1980-Present; PsychInfo 1984-present; the Institute for Scientific Information (ISI) databases of SCI-expanded and Social Sciences Citation Index (SciSearch) and the International Bibliography of the Social Sciences (IBSS) via the Bath Information and Dissemination Service (BIDS). References in articles were also used as a literature source in addition to hand searching of relevant journals.

2.1.1.2 Search terms

Search terms of: head and neck, cancer, carcinoma, malignant neoplasm, head and neck cancer, head, neck, oral, mouth, oral cancer, quality of life, QoL, HR-QoL, health states, assessment, were combined variously to search the databases. The term 'head and neck cancer' was also

exploded to include the following subject index terms: head and neck-neoplasms, hypopharyngeal-neoplasms, laryngeal-neoplasms, oropharyngeal-neoplasms, carcinoma, pharyngeal-neoplasms, tongue-neoplasms, tonsillar-neoplasms, esophageal-neoplasms, mouth-neoplasms, oral cavity-neoplasms, salivary gland-neoplasms, tracheal-neoplasms, submandibular gland-neoplasms, otorhinolaryngolic neoplasms, squamous cell carcinoma.

2.1.1.3 Limitations

The search was limited by including only literature published in the English language between the years 1980 to present and only involving human subjects.

2.1.2 RESULTS

The search yielded 479 articles, including 10 general reviews and a number of editorials. The reviews are listed in Table 2.1 and excluded from subsequent tables. The majority of the articles did not address quality of life issues. Articles were also discarded if they were abstracts, editorials, letters, and commentaries or did not report primary data. A total of 177 articles were deemed suitable for inclusion, however, due to this overwhelming volume of published material it is beyond the scope of this review to include details of every one of these studies. As reviews exist examining data published up to 1999, the present review will mainly concentrate on the literature post 1999 (2000 – present) but incorporating an overview of literature reviewed previously. From the literature search detailed above and hand searching relevant articles, over 50 original articles (published 2000 – present) were found.

The results section next provides a brief overview of the definition of quality of life (section 2.1.2.1) and a critical appraisal of HR-QoL instruments, including HNC specific measures (section 2.1.2.2). Section 2.1.3 presents the results of the literature search on the impact of HNC and treatment on QoL, considering both short term (<12 months after treatment) and

longer-term impacts (> 12 months). Section 2.1.1.4 discusses the limitations of the research presented and leads onto the main conclusions derived from the literature (section 2.1.5).

2.1.2.1 Definitions of 'quality of life'

There is wide variation in what is meant by 'quality of life' (QoL). The World Health Organisation has defined a high QoL as a 'state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.' Using the WHO's definition, global QoL could feasibly include a patient's psychological and emotional status and perceptions of satisfaction found in work, home life, religion, family, education or income. Assessing global QoL generally provides a broader picture of the impact of disease on an individual's life. In clinical practice, however, QoL generally refers to health-related quality-of-life (HR-QoL) which seeks to examine aspects of QoL thought to be impacted by a health or medical concern. Assessment of HR-QoL typically includes physical, psychological and social domains. Each domain may include measures that assess the patient's perception of symptoms, ability to function and disability (Troxel, Fairclough, Curran, & Hahn, 1998), therefore, measures of purely functional status are generally not considered here.

Table 2.1: Summary of review articles on QoL and psychosocial aspects of head and neck cancer (1980 – July 2005)

Author and Year	Period of search	Main focus of review	No. of studies reviewed in article	Comments
(Pruyn et al., 1986) The Netherlands	≤ 1984	A review of the psychosocial aspects of H&N cancer and factors that may influence rehabilitation.	References for N=10 (purported to have discussed N=117)	A condensed report of the main studies. Authors conclude that there was great variability in the reported rehabilitation and hardly any solid insight about what factors influence the rehabilitation process.
(Gotay & Moore, 1992) USA	1980-1990	A review of the definitions of QoL used in H&N cancer studies, how QoL has been measured and how QoL data has been used in treatment.	N=29. Only N=18 documented QoL in specific patient pop.	Only used articles that explicitly assessed components of the construct 'QoL'. Analysis revealed little consensus in definition or assessment of QoL. Deficiencies in QoL were briefly commented on.
(Dropkin, 1998b) USA	1996-1997	A review of four studies in relation to purpose, qol definition and measurement, findings and implications to nursing.	N=4	A very brief 2-page overview. Primarily as an introduction to the topic for otorhinolaryngology nurses.
(De Boer et al., 1999) The Netherlands & USA	1984-1996	A review of the physical and psychosocial correlates of H&N cancer.	N=50	Illustrates the enormous impact of HNC on the patient in terms of important physical symptoms and the main disturbances in psycho-social functioning and distress. Concludes that little is known of the long-term rehabilitation outcomes.
(Terrell, 1999) (USA)	Info. not systematically collected	Reviews definitions and principles of QoL assessment, identifies QoL instruments and summarise a selection of studies.	N=25 (Qol &/or functional assessment)	This article is not a literature review. Uses studies to provide examples but does not provide critical discussion of studies per se.
(Rogers, Fisher, & Woolgar, 1999) (UK)	1980-1997	Provides a summary of the concepts of QoL evaluation, reviews the studies and outlines QoL indices.	N=65 + description of N=27 commonly used QoL instruments	Comprehensive catalogue of studies but mainly a review and description of commonly used instruments. Does not comment on the outcome or critically review the studies in terms of assessment/ study design or what HR-QoL relates to in HNC patients
(List & Stracks, 2000) USA	1998-1999	Brief review of QoL in HNC with a focus on research and methodological developments in past year.	N=34	Also, briefly discusses issues of QoL measurement as well as challenges to data synthesis. Conclude that impaired function does not necessarily. lead to poor QoL.
(Frampton, 2001) UK	Info. not systematically collected	Review of factors that affect psychological adjustment and review of screening instruments for anxiety & depression.	N=16 (primary studies in review)	Both the disease and treatment are associated with considerable psychological distress. Review concludes with recommendations for reduction of distress at different stages.
(Ringash & Bezjak, 2001) Canada	1966-1999	A critical review of disease specific HR-QoL instruments for H&N cancer	N=8 disease specific QoL instruments were discussed	Review of EORTC QLQ C30/H&N35; FACT-H&N; HNRQ; QL-H&N; QLQ for adv HNC; QOL-RTI/H&N; HNQOL; UW QOL. Concluded that these vary widely in methodology, strengths and weaknesses. Validation of QOL instruments is ongoing.
(Schwartz, Patrick, & Yueh, 2001) USA	1989-1999	A review of quality of life outcomes in the evaluation of H&N cancer treatments. Includes comments on the use of terminology and study designs.	N=61	Authors concluded that 40 different instruments were used in the 61 articles reviewed. Only 11 studies (18%) explicitly tested a hypothesis. Many current QoL studies did not make an attempt to interpret results or comment on the biases from missing data.

2.1.2.2 HR-QoL measures

As it is accepted that 'HR-QoL' is a broad, multi-dimensional concept, a number of questionnaires have been developed that reflect this complex conceptual framework. There are three main categories of questionnaire that are commonly applied to assess the HR-QoL of HNC patients, performance questionnaires aside: global HR-QoL, general cancer HR-QoL and HNC specific HR-QoL. Global or generic questionnaires can be applied to patients with any disease or a 'normal' population and assess physical, psychological and social functioning (e.g. Short form Health Survey (SF-12), (Ware, Kosinski, & Keller, 1996); General Health Questionnaire (GHQ), (Goldberg & Williams, 1988). General cancer questionnaires focus on common symptoms and side-effects of cancer treatments (e.g. The European Organisation for Research and Treatment of Cancer (EORTC) core questionnaire, (Aaronson et al., 1993); The Functional Assessment of Cancer Therapy Scale (FACT-G), (Cella et al., 1993); Functional Living Index-Cancer Scale (FLIC) (Schipper, Clinch, McMurray, & Levitt, 1984). HNC specific HR-QoL questionnaires are intended to assess the specific impact of HNC and its treatment on an individual's HR-QoL in terms of oral function, which includes aspects of communication, swallowing, chewing, nutrition and cosmesis.

2.1.2.2.1 HNC specific HR-QoL measures

Eight *disease specific* HR-QoL instruments have been published for patients with HNC, with varying strengths and weaknesses. Reliability and validity studies using these instruments are still ongoing. The *European Organisation for Research into Treatment of Cancer Quality of Life Questionnaire for Head and Neck Cancer* (EORTC QLQ-C30/H&N35), (Bjordal et al., 1994), is a patient based, self-administered and multidimensional core and specific HR-QoL instrument developed across many cultural and language groups. The H&N module (H&N35) consists of 35 items from seven domains: pain, swallowing, senses, speech, social eating, social contact and sexuality, in addition to 11 single items (e.g. problems with teeth and mouth, sticky saliva, weight and painkillers). This extensive questionnaire demonstrated reliability, validity and

internal consistency in a trial of 500 patients (Bjordal et al., 1999), however, the social eating and speech domains did not show adequate reliability. Responsiveness to change over time was seen in most domains, except for domains of social contact and single items assessing dry mouth, mouth opening, sticky saliva and feeling ill.

The *Functional Assessment of Cancer Therapy- Head and Neck* (FACT-HNS), (List et al., 1996a), is also a self-administered, multi-item instrument consisting of 27 items from four domains – physical, social/family, emotional and functional, plus an 11 item H&N subscale. Item generation was based on 15 HNC patients and 5 'experts'. Item importance was determined by clinicians. Reliability and concurrent validity were found to be acceptable in this short questionnaire (D'Antonio, Zimmerman, Cella, & Long, 1996; List et al., 1996a) and responsiveness to change was also demonstrated (D'Antonio et al., 1996).

The *Head and Neck Radiotherapy Questionnaire* (HNRQ), (Browman et al., 1993a) was developed as an evaluative instrument to measure radiation induced acute morbidity and HR-QoL in patients with stage III or IV HNC. The interviewer administered scale consists of 22 items from six domains - skin, throat, oral stomatitis, digestion, energy and psychosocial. An unspecified number of oncologists, nurses and patients generated the items and reduction was judged by health care workers. Content and face validity are lacking and according to Ringash & Bezjak, (2001) it is questionable whether this instrument reflects the multiple dimensions of HR-QoL experienced over time.

The *Quality of Life Instrument for Head and Neck Cancer* (QL-H&N), (Morton & Witterick, 1995) is a short self-administered questionnaire with physical, social and psychological domains. The psychometric properties of this instrument are difficult to establish since the entire version has not been published.

The *Quality of Life Questionnaire for Advanced Head and Neck Cancer* (QLQ), (Rathmell, Ash, Howes, & Nicholls, 1991) is intended to discriminate between patients who undergo radiation treatment alone and those who have both surgery and radiotherapy. 19 items cover four domains of physical, functional/mood, psychological and attitude to treatment. No reliability data and minimal validity has been established for this instrument. Similarly, the *Quality of Life – Radiation Therapy Instrument Head and Neck Module* (QOL-RTI/H&N), (Trotti et al., 1998) is also intended to evaluate HR-QoL in patients undergoing radiotherapy. The self-administered questionnaire contains 25 items from four domains – functional, emotional, family/socio-economic and general, plus 14 items in the H&N module. Patients were not involved with item generation. Good internal consistency and test-rest reliability have been established (Trotti et al, 1998), although this instrument has yet to be tested with a sample larger than 34 patients.

The *University of Michigan Head and Neck Quality of Life* (HNQOL), (Terrell et al., 1997) is an interviewer administered questionnaire consisting of 21 items from four domains – pain, emotion, communication and eating. Patients and health care workers generated the items. Face and content validity have been found to be moderate (Ringash & Bezjak, 2001) although the authors of the instrument advise that it is used in conjunction with a general HR-QoL instrument. Test-retest reliability and internal consistency were reported to be high (Terrell et al, 1997). Construct and convergent validity were also adequate. The newer 20-item version has yet to be tested for reliability and validity.

The *University of Washington Quality of Life Questionnaire* (UW-QOL), (Hassan & Weymuller, Jr., 1993) is intended to discriminate between a variety of HNC sites and stages. However, it is primarily relevant to surgery patients. The self-administered questionnaire consists of 12 items: 9 disease-specific items (pain, chewing, swallowing, speech, shoulder disability, appearance, activity, recreation and employment) in addition to 3 items measuring, global HR-QoL, change in HR-QoL since diagnosis and overall QoL. It is not known whether patients were involved

with the item generation. Test-retest reliability is reported as very high with an acceptable internal consistency (Hassan & Weymuller, 1993). Responsiveness to change has also been reported (Deleyiannis, Weymuller, & Coltrera, 1997).

For a more detailed description and discussion of the psychometric properties of HNC specific HR-QoL measurement instruments, refer to Table 2.1, which includes three particularly useful and well-written reviews (Gotay & Moore, 1992; Rogers et al, 1999; Ringash & Bezjak, 2001).

2.1.3 THE IMPACT OF HNC AND TREATMENT ON HR-QOL

2.1.3.1 Study Design

In clinical research, HR-QoL is recognised as an important endpoint, as changes in treatment policy are aimed not only at maximising chances of survival, but also maintaining QoL (and possibly improving it) during treatment and long-term. Three basic types of study have been employed in HNC HR-QoL research: cross-sectional, prospective and case-control. Cross-sectional studies provide a snapshot evaluation from a specific time period but may have reduced sensitivity due to patient under-reporting (Breetvelt & van Dam, 1991). More importantly, without pre-treatment data, specific HR-QoL cannot be directly attributed to the effects of disease and treatment. Longitudinal (prospective) studies allow for the analyses of the impact of treatment, although selection bias is created due to loss of patients over the study period because of recurrent illness and death. Case-control studies allow for a comparison between the HR-QoL of the sample under study and another population, for example, another clinical sample or normative data.

In the past, the majority of published studies in this field were cross-sectional in design, but in the last few years the majority are now prospective. However, there have been very few studies published that have used control groups or randomised treatment groups. A considerable number of studies have been conducted on patients with oral or laryngeal cancer alone, and

care has to be taken when comparing heterogenous cohorts of patients with respect to differing cancer sites and hence differing associated problems.

2.1.3.2 Short-term impact on HR-QoL (≤12 months post-treatment)

2.1.3.2.1 Prospective studies

Unsurprisingly, the majority of studies have found a temporary deterioration in HR-QoL in the first three months after treatment (de Graeff et al., 1999a; Deleyiannis et al., 1997; Hammerlid et al., 1997b; Hammerlid et al., 1997a; Hammerlid, Mercke, Sullivan, & Westin, 1998; Hammerlid et al., 2001a; Kohda et al., 2005; List et al., 1999; Lloyd, Devesa-Martinez, Howard, & Lund, 2003; Rogers, Lowe, Brown, & Vaughan, 1998; Rogers, Humphris, Lowe, Brown, & Vaughan, 1998; Rogers, Lowe, & Humphris, 2000), particularly in domains of physical and role functioning, probably caused by treatment itself. However, in the 12 months following treatment, the results are less consistent. In a study of 105 HNC patients by Gritz et al, (Gritz et al., 1999) despite improvements in some physical functioning domains one month into recovery from treatment, patients still reported a decline from 1 month to 12 months in the domain of marital and sexual functioning and no significant improvement in other HR-QoL domains (Cancer Rehabilitation Evaluation System- Short Form (CARES-SF)). These results highlight that, even with functional improvement, HR-QoL is impacted in other ways and for a significant time period after treatment. However, baseline (pre-treatment) levels of HR-QoL were not presented and it is unknown whether there were any significant differences between baseline HR-QoL and scores at 1 and 12 months. Functional status reflecting normal activity (as measured by the Karnofsky Performance Scale) was reached within 12 months (Gritz et al, 1999). The findings of this particular study contrast with several prior reports that indicate a gradual improvement in HR-QoL within the same time frame, in primary radiotherapy patients (De Boer et al., 1995; Moore, Parsons, & Mendenhall, 1996) and with surgically treated patients (De Boer et al., 1995; List et al., 1996b).

Paradoxically, despite the initial decline in physical aspects of HR-QoL, pain, mood and anxiety scores (UW-QoL) have been shown to significantly improve with surgical patients, at all post-operative time points (up to 12 months) compared to pre-operative scores (Lloyd et al., 2003) and similarly, with emotional functioning (EORTC QLQ-C30 & HN35) (Bjordal et al., 2001; Schliephake & Jamil, 2002). However, in one study of 20 patients treated with radiotherapy (Epstein, Robertson, Emerton, Phillips, & Stevenson-Moore, 2001), emotional functioning scores initially declined after treatment (as with all aspects of HR-QoL) but showed a gradual increase at 6 months in line with the other domains (EORTC QLQ-C30). None of these studies reported multivariate analyses.

2.1.3.3 Long-term impact on HR-QoL (>12 months post-treatment)

2.1.3.3.1 Prospective studies

Until relatively recently, no prospective studies had been published with a follow-up of more than 1 year. However, several studies have now been reported with follow-up data of 2 and 3 years. For example, de Graeff et al (2000b) conducted a three-year prospective study of 107 patients with mixed site HNC treated with surgery and/or radiotherapy. It was found that the majority of HR-QoL domains, (as measured by the EORTC QLQ-C30+H&N35), had returned to pre-treatment levels after 12 months with little change afterwards. However, at 36 months, domains of: physical functioning, taste/smell, dry mouth and sticky saliva were still significantly worse compared with baseline. The authors conclude that the magnitude of these differences was indicative of minor/moderate clinically relevant changes. Despite the longer-term deterioration of several physical symptoms and functioning scales, a gradual improvement of emotional functioning and depression (as measured with the CES-D) was reported.

A similar pattern was also reported in a 2 year longitudinal study of 201 HNC patients (Morton, 2003). Overall QoL (as measured by a modified 10 item version of the Life Satisfaction scale (Morton et al., 1995; Warr, Cook, & Wall, 1979)) improved significantly from

time of diagnosis to 24 months (p=0.005), although there was no significant difference between 12 and 24 months. Psychological distress (GHQ-12) was significantly increased at 3 months but returned to at least pre-treatment levels by 12 and 24 months. However, all 201 patients at baseline were included in these analyses when only 91 had completed questionnaires at 2 years. An analysis of these 91 patients demonstrated that only global QoL (life-satisfaction) was significantly better at 2 years (p=0.006) and psychological distress was not. Amongst patients with cancer of the supraglottis and glottis, there was more difficulty speaking (p≤0.005) at 2 years post-diagnosis but not amongst patients with oral/oropharyngeal cancer. Many other mean scores of single item measures of somatic and physical dysfunction were found to increase over the 24 months follow-up.

2.1.3.3.2 Cross-sectional studies

Cross-sectional studies have allowed the exploration of HR-QoL over longer time periods since treatment. Patients treated with primary surgery are considered to have a poor physical and psychological out-come as a result of mutilating surgery, however, advances in microvascular free tissue transfer has reduced the extent of physical deformity but with little improvement in function (Vaughan, Bainton, & Martin, 1992). Rogers et al (1999) conducted a cross-sectional study comparing 38 patients (out of an original cohort of 220 patients) treated 5-10 years after primary surgery for oral and oro-pharyngeal cancer, with 25 patients treated a year previously (Rogers, Hannah, Lowe, & Magennis, 1999). The results at one year were similar to longer-term (5-10 year) survivors, suggesting that most of the longer term gain is achievable within one year. Indeed, UW-QoL scores in the longer-term group were better than at one year in all domains except shoulder function. This may have been due to the tendency towards radical neck dissection as compared to the function preserving neck dissections favoured now (see section 2.1.3.5.1.3). Despite the overall good level of functioning, it was found that a significant number of patients continued to experience severe problems, particularly in domains of: disfigurement, emotional and cognitive functions and chewing

related functions (e.g. dry mouth, sticky saliva and trouble eating). Half of the longer-term survivors reported the use of painkillers in the last week. However it is not known whether this was specifically related to head and neck pain or not. Other cross-sectional studies providing long term data since 1999 have also shown similar results, whereby specific symptoms of the head and neck area (i.e. problems with speech and eating) are more likely to affect HR-QoL at 2-10 years post-treatment (Klug et al., 2002), and not surprisingly, are significantly worse than in non-cancer controls (Fang et al., 2002).

Several other survivor studies have demonstrated the long-term emotional effects of cancer and treatment. A European radiation therapy trial conducted between 1979 and 1984 randomly assigned 845 HNC patients into two radiotherapy schedules. The trial demonstrated no difference in survival or late effects between the study arms. However, 7-11 years later, a cross-sectional study of the HR-QoL of more than 200 of the trial survivors showed that emotional and social function were both adversely affected long-term if surgery was conducted as part of treatment (Bjordal, Kaasa, & Mastekaasa, 1994). Long-term psychological distress (using the General Health Questionnaire (Goldberg et al., 1988)) was also reported in 30% of the same cohort (Bjordal & Kaasa, 1995). This distress was found to be more pronounced in those with impaired cognitive function, impaired social function and pain. Pourel et al (2002) reported similar results in a study of 113 patients at 2 to 9 years post-treatment (Pourel et al., 2002). Compared with the general population, the three scores indicating the most impaired HR-QoL (EORTC-QLQ-C30) were emotional and social functioning and fatigue. In addition, the physical functioning, role functioning and pain scores did not significantly differ from the general population.

One cross-sectional study compared the results from HNC patients 2 and 3 years post-diagnosis with general population norms (Hammerlid & Taft, 2001c). Hammerlid & Taft (2001) used the Swedish version of the SF-36 Health Survey (Sullivan & Karlsson, 1995) and

the EORTC QLQ-C30 & H&N35, to examine how long term survivors of HNC 3 years after diagnosis (n=151) compared with age and gender matched or adjusted norms of Swedish and Norwegian populations (Hammerlid, Mercke, Sullivan, & Westin, 1996; Hjermstad & Fayers, 1998b; Hjermstad & Fayers, 1998a; Sullivan & Karlsson, 1994). Comparison of the SF-36 demonstrated that only the role-physical functioning domain was significantly worse in the HNC patients compared to the population sample (p=0.008), although clinically worse for domains of role physical functioning and role-emotional functioning. A gender difference was noticed, whereby female HNC patients (n=42) scored the same or better than the female reference group on all 8 SF-36 domains. However, for males, an opposite pattern was found whereby the population sample scored better than the HNC patients (n=93) on 7 of the 8 domains. A comparison of the EORTC QLQ-HN35 showed that HNC patients scored significantly worse compared to the population on all scales and single items except for coughing and feeling ill. An analysis of the EORTC QLQ-C30 by gender, again showed that female cancer patients scored better on 13 of the 15 scales and single items compared to the normative population but males only scored better on 7 of the 15 scales.

The results of this study indicate that the general health status of long-term survivors is comparable or even better than age and gender matched normative populations. However, despite this, patients still report significant problems with more specific functions such as, social eating, pain and swallowing 3 years after diagnosis. This highlights the importance of measuring HR-QoL with specific as well as generic questionnaires in order to elicit a more accurate picture of long standing problems. However, these results also illustrate that despite still having specific limitations, patients show functional adaptation both physically and emotionally over time.

Although these cross-sectional studies cannot provide any pre-treatment comparison data to test for causal relationships, they suggest that the emotional and social consequences of HNC to survivors remain even after a substantial time has elapsed since treatment.

2.1.3.4 Patient's priorities regarding treatment outcomes and QoL

Despite the surfeit of publications measuring HR-QoL within this patient group, little has been published regarding patient priorities in terms of treatment outcomes or QoL. The crude effects of different treatment regimens on patients functioning is well recognised, therefore, patients can be more adequately informed as to the likely effects of treatment. Not much is known, however, as to how patients make treatment decisions when faced with the probabilities of survival versus likelihood of serious morbidity.

In an early innovative 'trade-off' study involving healthy participants (McNeil, Weichselbaum, & Pauker, 1981), it was found that people were willing to 'trade-off' years of life in order to retain normal vocal function, after being educated about the effects of having a laryngectomy. However, none were willing to trade off more than 5 years survival. Although, this study was influential in suggesting that for some people quality of life was preferable to quantity of life, it is questionable whether one can extrapolate healthy patients priorities, using a standard gamble technique, to the priorities one would actually have when faced with laryngeal cancer.

More recently, a few studies have sought to examine patients' preferences among treatment effects. Sharp et al (1999) designed a new instrument to allow patients to prioritise 12 treatment effects and tested it on a cross-sectional sample of 19 patients pre- and post treatment (Sharp et al., 1999). The instrument revealed considerable variability in how patients prioritise treatment effects leading the authors to conclude that some patients may adjust to certain disabilities over time, despite the study being based on a cross-sectional sample of pre-

and post-treatment patients. The variation evidenced may have been due to different treatment effects being experienced at different stages of recovery.

List et al (2000), examined newly diagnosed, advanced stage HNC patients' pre-treatment preferences of a series of possible late stage effects of treatment (List et al., 2000). Results indicated that at this time point, survival was top priority amongst patients. This data is consistent with newly diagnosed patients' willingness to accept highly toxic treatment with risk of chronic dysfunction for any chance of benefit (Slevin, Stubbs, & Plant, 1990). Studies of HR-QoL outcome typically focus on speech, swallowing and other functions that are affected but the results of List et al., (2000) demonstrate that items relating to energy levels and normal activities were more frequently ranked in the top three considerations than items of appearance, chewing and being understood, irrespective of treatment. However, being newly diagnosed, patients had not yet experienced the morbidity in question and patient priorities may well change over time and with experience. With respect to HR-QoL and performance status, patients tended to place higher priorities on areas that they were experiencing difficulties with.

In the only study to report patients' importance ratings of HR-QoL longitudinally, Rogers et al., (2002) found that both pre- (n=48) and post-treatment (n=35) there was little correlation between importance rating and actual HR-QoL domain score (Rogers, Laher, Overend, & Lowe, 2002), thus indicating that patients do not necessarily rate their current functional limitation as being most important. This finding is supported by Deleyiannis et al., (1999), who reported that following laryngectomy the severity of functional disability did not correlate with its importance (Deleyiannis, Weymuller, Jr., Coltrera, & Futran, 1999). At all time points (baseline, 6 and 12 months), patients tended to rate speech, chewing and swallowing as more important than other HR-QoL domains (as measured by the UW-QoL). No studies have been

found that have attempted to explore head and neck cancer patients' priorities or ratings outside of functional or standard HR-QoL domains.

Further prospective studies may help to identify whether particular functional problems associated with treatment are more amenable to adaptation than others and to what extent and why priorities change over time.

2.1.3.5 Factors associated with or predictive of HR-QoL

Numerous descriptive studies of HR-QoL in HNC patients have been published previously, recently, emphasis has been on the relationship between patient demographic factors, specific disease or treatment related variables, and HR-QoL.

2.1.3.5.1 Disease or treatment related factors

2.1.3.5.1.1 Cancer site and stage

Cancer site and stage are often interrelated, with patients with carcinoma of the hypopharynx, nasopharynx and oropharynx more likely to present with advanced stage of disease (Jones & Stell, 1991; Vernham & Crowther, 1994). Advanced disease in HNC has been reported as associated with poorer pre-treatment HR-QoL (Hammerlid et al., 2001a) and a worse initial post-treatment decline in HR-QoL (Bjordal et al., 2001; Weymuller et al., 2000) with no return to baseline HR-QoL after 24 months (Weymuller et al., 2000). Similarly, a cross-sectional study of 60 patients with oropharyngeal cancer (Allal, Nicoucar, Mach, & Dulguerov, 2003) found that tumour size was important when examining the effects of treatment. In patients with smaller tumours (T1-T2), there was no significant difference in HR-QoL between RT and surgical/RT treatment groups, whereas with larger tumour sizes (T3-T4) patients having undergone surgery/RT had significantly worse HR-QoL. In addition, the time since treatment for the surgical patients was much longer (median: 78 months, range: 16-200 months) than that of the RT group (median: 27 months, range: 12-82 months). However, no multivariate analyses

were conducted on these data and it was not known whether stage corresponded with tumour size in these patients as nodal involvement was not reported. Other studies also provide support for the finding that patients with later stage tumours score significantly worse on HR-QoL than those with smaller tumours (Rogers et al., 2000; Hammerlid et al., 2001a; Rogers, Lowe, Fisher, Brown, & Vaughan, 2002). However, similar to Allal et al. (2003), significant treatment effects are also reported and not controlled for. In contrast, the results from a cross-sectional study of 135 HNC patients showed that stage at presentation did not differentiate HR-QoL at three years after treatment (Hammerlid et al., 2001c). It is worth noting that the level of tumour staging used in studies may differ, with respect to whether details of nodal involvement is known, which may influence the treatment and therefore potentially HR-QoL. Indeed, results from a longitudinal study of 91 HNC patients (Morton, 2003), found that nodal status (N-status) was significantly associated with a single-item measure of overall QoL (Warr et al., 1979) and several single HR-QoL items such as head and neck pain and difficulty swallowing, whereas tumour size (T-stage) was not. T-stage, however, was positively correlated with a measure of psychiatric distress (GHQ). The inconsistency in the literature regarding the role of cancer stage or tumour size is further confounded by the results from a 3-year prospective study (de Graeff et al., 2000a). In a multivariate analyses of 107 HNC patients, subgroup (oral/oropharynx vs. larynx), stage of cancer and treatment were found to have significant effects on HR-QoL, particularly head and neck symptoms (EORTC H&N35). It was noted that these clinical factors were associated with physical symptoms but not with any psycho-social functioning or depressive symptoms (CES-D).

The differences in HR-QoL due to tumour site are well reported in the literature with different tumour sites affecting different aspects of HR-QoL (Hammerlid et al., 2001a). Patients with pharyngeal cancer tend to have the most functional problems, followed by oral cancer then laryngeal cancer (Bjordal et al., 2001; Hammerlid et al., 2001a). This is in line with the tendency for these cancers to be diagnosed at different stages. At 1 year post-treatment, patients with

pharyngeal cancer reported clinically worse scores compared with patients with laryngeal or oral cancer on many HR-QoL domains, most of which related to swallowing and nutrition (Bjordal et al., 2001).

2.1.3.5.1.2 Treatment modality

Choice of treatment is often dependent on the site and stage of disease, therefore, it is often not possible to disentangle treatment effects from disease related effects. Studies have shown that there are specific consequences to HR-QoL as a result of different types of treatment.

2.1.3.5.1.2.1 Radiotherapy

Radiotherapy (RT) patients mainly report xerostomia (dry mouth) and related difficulties, namely problems with chewing and swallowing food, recurrent infections, mucositis, increased incidence of dental caries and sometimes problems with speech (Ackerstaff et al., 2002; Epstein et al., 1999; Tschudi, Stoeckli, & Schmid, 2003). The majority of RT patients note a decrease in the amount of saliva or a change in its consistency. Studies have shown that long-term xerostomia has a more detrimental effect on QoL than voice function, which is often considered worse (Stoeckli, Guidicelli, Schneider, Huber, & Schmid, 2001). Recently, the severity of xerostomia after radiotherapy has been reduced by using 3-D treatment planning (3-DTP) and intensity –modulated radiotherapy (IMRT). The goal of this has been to spare the major salivary glands while delivering the fully prescribed doses to the target (Eisbruch et al., 1999; Eisbruch et al., 2001). Several papers have examined the salivary function and HR-QoL of patients receiving parotid sparing RT (Henson, Inglehart, Eisbruch, & Ship, 2001; Lin et al., 2003).

Henson et al. (2001) and Lin et al. (2003) both conducted prospective, 12 month longitudinal studies examining whether the preservation of saliva post RT to the neck region resulted in better xerostomia-related QoL. Results were similar between the 20 HNC patients recruited in

the Henson et al. (2001) study and the 36 HNC patients recruited in the Lin et al. (2003) study. Key findings were the strong relationships demonstrated between all HNQOL domains and patient reported xerostomia, and the effect of time on xerostomia-related QoL. The findings suggest that despite parotid sparing RT, salivary flow rates and HR-QoL decrease at the completion of RT but both improve over the following 12 months.

2.1.3.5.1.2.2 Radiotherapy versus Surgery

Many of the major functional deficits commonly resulting from surgery have been alleviated by microsurgical reconstructive techniques (Vaughan et al., 1992). However, patients still face a certain amount of morbidity following surgery. Some of the issues more pertinent to surgical treatment are; difficulties with appearance (Dropkin, 1997), speech (Pauloski, Logemann, Colangelo, & et al, 1998), swallowing (Logemann, Pauloski, Rademaker, & Colangelo, 1997), chewing (Curtis, Plesh, Miller, & et al, 1997), oral rehabilitation (Rogers, McNally, Mahmood, Chan, & Humphris, 1999), nutrition (Beeken & Calman, 1994) and shoulder function (Kuntz & Weymuller, Jr., 1999).

Compared to surgery with or without post-operative RT, it has been suggested that non-surgical treatments are associated with superior functional outcomes in oral cancer (Campbell, Marbella, & Layde, 2000; Harrison, Zelefsky, Armstrong, Carper, & Gaynor, 1994). A recent cross-sectional study of 60 patients treated for oropharyngeal cancer with either RT (with or without chemotherapy) (n=40) or surgery and post-operative RT (n=20) provides support for this assertion (Allal et al., 2003). Using the Performance Status Scale for Head & Neck Cancer (PSSHN) (List et al., 1996a), Allal et al. (2003) found significant group differences for the understandability of speech domain but not for other PSSHN domains or any functional domains of the EORTC QLQ-C30. However, when the patients were divided into two groups based on tumour size (T1/2 vs. T3/4), significant differences emerged. Patients with larger tumours (T3/4) who had undergone surgery, showed significantly worse scores on the PSSHN

for; eating in public (p=0.002), understandability of speech (p=0.005) and normalcy of diet (p=0.008) than those with larger tumours who had non-surgical treatment. In addition, the T3/4 surgical group reported significantly more pain than the T3/4 RT group (p=0.008). However, patients with smaller tumours treated surgically, had significantly better scores for social functioning (EORTC QLQ-C30) than RT patients.

As before, it is also interesting to note that the time since treatment for these surgical patients was much longer (median: 78 months, range: 16-200 months) than that of the RT group (median: 27months, range: 12-82 months). Although multivariate analyses were not conducted, these results suggest there may also be important time considerations when comparing the HR-QoL between treatment groups. For example, high dose radiotherapy is associated with late toxic effects, therefore, depending on the timing of HR-QoL measurements, RT patients may still be experiencing serious side-effects of treatment. At a similar time point, surgical patients may be entering their recovery phase. Evidence suggests, however, that after 1 year, RT alone produces functionally superior results and better HR-QoL.

A study by Tschudi et al. (2003) provides partial support for a differential treatment effect on HR-QoL in 99 post-treatment oropharyngeal cancer patients. Functional (EORTC QLQ-C30) scores were reported to be unaffected by treatment type (surgery, RT, or surgery +RT), however, comparison of the head and neck specific scores (EORTC QLQ-HN35) revealed significantly less problems with swallowing (p=0.006), social eating (p=0.007), social contact (p=0.008), dry mouth (p<0.0001), sticky saliva (p=0.0001) and mouth opening (p=0.001) in non RT patients. Surgical patients reported significantly less pain (p=0.04) than non-surgically treated patients. All analyses were univariate and therefore, no adjustments were made for other potentially confounding factors.

Disregarding the treatment modality, studies suggest that maintaining the ability to wear a denture is also an importance factor in HR-QoL, affecting mastication, appearance and speech (Terada et al., 2003).

2.1.3.5.1.3 The impact of neck dissection on HR-QoL

Neck dissection (ND) is often needed in the management of the HNC patient. Known complications and morbidities after ND often include numbness and/or pain in the neck or ear, shoulder and neck discomfort, functional problems with the arm and shoulder and lower lip weakness. Preservation of the spinal accessory nerve (i.e. selective ND) has been found to be associated with better HR-QoL in the few studies that have reported the impact of ND on HR-QoL. In a cross-sectional study of 51 HNC patients, Shah et al, (2001) used their own validated Neck Dissection Quality of Life Questionnaire (Shah, Har-El, & Rosenfeld, 2001) and found that neck tightness and shoulder discomfort were the most common symptoms that interfered with daily life after ND. The exact time since ND was unreported but was in the range of <11 months to >36 months. Multivariate analyses indicated that the type of ND performed (radical versus selective) ($p=0.03$) and chemotherapy ($p=0.01$) explained 21% of the variance in neck-dissection specific HR-QoL ($R^2=0.21$). Time since surgery was not significant. Tumour stage and radiation therapy were not entered into the regression model due to their association with type of ND. Similarly, Taylor et al (2002) devised and validated their own Neck Dissection Impairment Index (Taylor et al., 2002) to investigate factors influencing QoL in a convenience sample of 54 HNC patients (List et al., 1996a). Using multiple regression, the variables contributing most ($R^2=0.44$;$p<0.001$) to shoulder-related HR-QoL were, age ($p=0.1$), weight ($p<0.001$), radiotherapy ($p=0.04$) and type of ND ($p=0.14$).

In another cross-sectional study, Terrell et al (2000) (Terrell et al., 2000) also found that the spinal accessory nerve status (type of ND) ($p=0.002$), HR-QoL emotion score ($p=0.0001$), as measured by the HNQoL (Terrell, Nanavati, Esclamado, Bradford, & Wolf, 1999), and time

since treatment (p=0.001), were all independent predictors of HNQoL 'shoulder or neck' pain score in 175 HNC patients. This indicated that those who had a selective ND, better HR-QoL emotion scores and surgery over 2 years previously, were less likely to score highly for 'shoulder/neck' pain. Kuntz & Weymuller (Kuntz et al., 1999), analysed data from 84 HNC patients who had undergone ND and had completed a pre-treatment and 6 & 12 month post-treatment UW-QoL (Hassan et al., 1993) 'shoulder domain'. They also found that radical ND was associated with worse pain scores after treatment. There was a significant improvement in pain over time with selective ND only (p=0.02). However, it was also found that improvement in pain was also associated with T1-T3 tumours. Multivariate analysis was not performed.

2.1.3.5.2 Demographic factors

2.1.3.5.2.1 Gender

Data from studies investigating the influence of gender on HR-QoL are conflicting. Some studies report no gender differences at any stage of assessment (Rogers et al 1998; Morton, 2003) whereas others suggest females report worse symptoms and physical functioning (Allison, Locker, Wood-Dauphinee, Black, & Feine, 1998; De Boer et al., 1995; de Graeff et al., 2000a; Languis, 1995) and worse emotional functioning over time than males (Hammerlid et al., 2001a).

Conversely, results from a longitudinal study using a normative population sample (n=871) for comparison purposes, found that females 3 years after diagnosis scored the same or better than males on all domains of the SF-36 than an age and gender matched sample (Hammerlid et al., 2001c). Comparisons between HNC patients only (n=135) showed that females scored better than males on all scales except mental health. Although many of the gender differences in domains were clinically significant (physical, role physical, general health, vitality and role emotional), none proved statistically significant. Moreover, regression analyses with gender, age, disease stage, tumour site, treatment modality and number of co-morbidities as predictor

variables, indicated that gender did not explain a significant proportion of the variance in any SF-36 domain (Hammerlid et al., 2001c).

2.1.3.5.2.2 Age

Similarly to gender, the influence of age on HR-QoL is also not consistent in the literature. Studies have reported that age has no influence on HR-QoL except on physical functioning (de Graeff et al., 2000a; Rogers et al., 1998). A recent study comparing the HR-QoL of 54 elderly (≥70 years) and 75 younger patients (45-60 years) with HNC after surgery, supports this finding (Derks, de Leeuw, Hordijk, & Winnubst, 2003). The groups proved significantly different for gender, site, co-morbidities, Karnofsky performance status, radiotherapy and alcohol and tobacco use, with older patients scoring worse for co-morbidity and performance status. There was no age group difference in tumour stage. Despite this, no significant differences were found in HR-QoL (EORTC QLQ-C30 and QLQ-H&N35) or depression (CES-D) between the younger and older samples both before and 3 months after surgery, controlling for tumour site.

Advancing age was found to be predictive of worse global HR-QoL in a study by Allison et al. (1998). Univariate analysis demonstrated no association of age with global HR-QoL (EORTC QLQ-C30) in a cross-sectional sample of 188 HNC patients but multivariate analyses revealed age to be a significant predictor ($p=0.0003$), in addition to employment (see later), gender, dental status, stage and site ($F=5.117, p<0.0001; R^2=0.21$).

Paradoxically, older patients (>75 years) have been reported at diagnosis as having clinically better HR-QoL scores on emotional functioning than younger patients despite having worse scores for domains reflecting physical functioning and symptoms. Significant correlations between high age and better social functioning ($p<0.05$) and emotional functioning ($p<0.01$)

were also reported by Hammerlid et al (2001a) (Hammerlid et al., 2001a). However, these were all based on univariate analyses.

Age as an independent variable has been divided into different groups for purposes of analyses, which may explain the contradictory findings amongst the literature. For example, Pourel et al. (2002) found no age effect on HR-QoL in multivariate analyses using age dichotomised around the median (≤61 vs.>61yrs), whereas Allison et al. (1998) used a continuous measure of age in their study. In addition, many of the studies used different time frames to assess HR-QoL.

2.1.3.5.2.3 Ethnicity/ cultural factors

No studies have reported the effects of ethnicity on the HR-QoL of HNC patients. The majority of papers in this area do not describe the ethnicity of their patient samples. A recent cross-sectional study by Morton (2003) attempted to compare the HR-QoL in two geographically separate and culturally distinct populations. The 45 pairs of patients recruited from Canada and New Zealand were largely Caucasian and matched for age, gender, primary site, T and N stage and overall cancer stage. Psychological distress (GHQ-12) and country of residence were found to account for more than 40% of the variance in global QoL (LS-10) (Morton, 2003). The exact figures are not provided.

Although there were treatment differences between the groups, these did not appear to contribute to overall QoL on multivariate analysis. From analysis, it was suggested that patients from Canada had a worse HR-QoL than patients from New Zealand. The only other cross-cultural data on the HR-QoL of HNC patients was supplied from Europe as a result of a large-scale validation study of the EORTC QLQ-H&N35 (Bjordal et al., 1999; Bjordal et al., 2000). Although baseline differences in HR-QoL were found between patients from Norway, Sweden and The Netherlands, any variation was attributed to differences between patients (site, stage and performance status).

2.1.3.5.2.4 Employment and educational level

Employment status and educational level of the patient are rarely analysed in relation to HR-QoL in this patient group but in the few papers that have, results are conflicting. No relationship was found between educational level (high school diploma or less vs. higher level) and HR-QoL (FACT-G & HNS, UW-QoL and PSS subscales of eating in public, speech and normalcy of diet) with multivariate analyses of a cross-sectional sample of 50 HNC patients up to 6 years post-surgery (Long et al., 1996). However, a prospective study (Sehlen et al., 2002) of 83 HNC patients 6 weeks after radiotherapy, found that five socio-demographic variables (no children, unemployment, male sex, low secondary education and ethanol abuse) could predict 26% of the variance in HR-QoL (FACT-G). It was also emphasised that only socio-demographic variables could predict HR-QoL and not the various clinical and treatment related factors that were also analysed.

Four studies highlight the relationship between poorer HR-QoL and unemployment. Allison et al. (1998) demonstrated that a range of clinical and socio-demographic factors could explain global HR-QoL (EORTC QLQ-C30) in a cross-sectional study of 188 post-treatment HNC patients. A multivariate model including clinical (dentate, stage and site) and socio-demographic factors (unemployment, age and gender) was found to explain a significant ($p<0.0001$) 21% of the variance in HR-QoL (although this was not adjusted R^2). The three strongest predictors of HR-QoL were unemployment ($p=0.0001$), age ($p=0.0003$) and gender ($p=0.017$).

Similar results regarding the relationship between unemployment and HR-QoL were also reported by Fang et al. (2002) using the SF-36, Pourel et al. (2002) using the EORTC QLQ-C30 global QoL and Sehlen et al. (2002) using the FACT-G.

2.1.3.5.2.5 Marital status

Long et al. (1996) found that married patients and those living with someone else had higher HR-QoL (using the FACT-G but not with the FACT-HNS or UW-QoL). However, Allison et al. (1998) failed to find a significant relationship between living arrangements (living alone vs. living with others) and HR-QoL, although the mean global QoL score was higher for those living with someone (mean=64;95% CI:60-68) rather than living alone (mean=60; 95% CI:51-69). Similarly, Fang et al. (2002) failed to find a relationship between any of the functional domains of the SF-36 and marital status in 182 post-treatment nasopharyngeal patients (Fang et al., 2002).

2.1.4 LIMITATIONS OF RESEARCH

Great variability has been shown in the HR-QoL of patients with HNC. The minority of research studies to date have been longitudinal in design and very few have explicitly tested hypotheses or used psychological models. Potential biases within the data are likely to have been uniform across studies, namely, unavoidable selection bias for treatment decisions, since randomisation is rarely feasible or ethical. In addition, variation in HR-QoL may be accounted for by the heterogenous samples often included in analyses, in terms of site, stage and treatment modality. Although many studies do not have the statistical power for sub-analyses by site, stage or treatment modality, multivariate analyses have not been attempted in order to control for the effect of other variables on HR-QoL. When stratification by site, stage and treatment is carried out, the resultant small sample numbers do not achieve enough statistical power to allow for accurate between-groups comparisons. This is especially problematic for the longitudinal analyses of advanced stage tumours, where 40-50% of patients do not survive for 2-year follow-up (Weymuller, Jr. et al., 2000). This is highlighted by the cross-sectional study by Rogers et al (1999), in which only 38 (17%) of the original 220 patients were included in the longitudinal analysis. The small number of survivors after several years makes Type 2 statistical

errors more likely when comparing groups. In addition, it is likely that those who drop-out are more at risk of poor HR-QoL.

Frequently in cross-sectional studies, the time since treatment and baseline HR-QoL are not included in the analyses, thereby limiting the validity of the results. Important time differences in psychological adaptation and symptom perception may occur, which would be obscured when the patient sample shows great variation in time since treatment.

Although particular types of HNC have been grouped together for analyses because they have been considered sufficiently homogenous, the question of whether they are homogenous in terms of HR-QoL has never been explored. In multivariate analysis, the complex interaction between stage, site and treatment means that it is likely that one of these factors is erroneously forced out of the statistical model.

This review highlights the insensitivity of general measures of HR-QoL (for example, the EORTC-QLQC30 or SF-36) to accurately illustrate long-term H&N specific problems or treatment related effects. Many studies that have failed to find differences between treatment groups or site/stage of cancer have frequently used general measures of HR-QoL. Many studies have also not interpreted HR-QoL scores in terms of clinical relevance.

Weymuller et al (2000) have reported the problems when examining global HR-QoL scores only, particularly when assessing the impact of treatment. The functional changes created by different treatment modalities affect different domains and this causes a cancellation effect when examining total scores only. Therefore, using a global or total score for examining effects of treatment induced change in HR-QoL may not be appropriate.

None of the studies assessed the effect of ethnicity on QoL, probably due to the small sample sizes involved. Although a few of the measurement instruments have been validated cross-culturally, many of the larger samples published have been based on white, frequently Scandinavian or Dutch, populations. Patient's perceptions of HR-QoL and factors affecting adaptation could conceivably differ across countries and cultures.

2.1.5 CONCLUSIONS

Treatment for HNC results in medium term morbidity and depression, much of which has been shown to improve within one year. In the long-term, despite an initially high level of depression, there is a gradual improvement in psychological functioning and global QoL over the next few years. However, there is subgroup of patients who continue to experience high levels of psychological morbidity years after treatment and it is important to note that this has been shown to be unrelated to physical functioning.

Although a patient's characteristics are clearly important, there is no clear evidence for the impact of disease and treatment on outcomes such as QoL and many studies have reported that somatic symptoms and scores of dysfunction are not associated with emotional distress or QoL either (de Graeff et al., 1999b; Hammerlid et al., 1998). In addition, socio-demographic factors and the majority of clinical/treatment related factors are not amenable to modification.

Authors in the field are beginning to acknowledge that an individual's QoL is probably determined more by their perceptions of the disease than the disease itself (Sehlen et al, 2002) and adaptational processes may be responsible for distorted interpretations of changes in QoL over time. However, it has been argued that the absolute changes in QoL are not important but the experience of the patient at the time of completing the questionnaire is (by definition the actual standard). If QoL is defined as the perceived discrepancy between what one has and

what one wants, then this implies that QoL should always be related to the actual standard (de Graeff et al, 2000).

To date there has been little or no attempt to explain these discrepancies in QoL and although factors such as stage, site of disease and type of treatment, have some impact on HR-QoL, it is unclear what additional factors account for the large variation evidenced in patient outcomes.

In the last few years, more interest has been generated in the area of psychological factors (although most commonly the influence of depressive symptoms) to account for variation in HR-QoL. The following section (2.2), systematically appraises the literature for answers to what these 'other factors' may be and whether they are open to modification, as the primary value of understanding individual variation in HR-QoL is to minimise the impact of HNC on a patient's life. By understanding the relationship between HR-QoL and potentially modifiable patient factors, such as psychological factors, interventions can be designed with the aim of maximising a patient's long term QoL.

PART 2: ARE PSYCHO-SOCIAL AND BEHAVIOURAL FACTORS RELATED TO HEALTH RELATED- QUALITY OF LIFE IN PATIENTS WITH HEAD AND NECK CANCER? A SYSTEMATIC REVIEW

This chapter has been published: Llewellyn CD, McGurk M, Weinman J. (2005) Are psycho-social and behavioural factors related to Health Related- Quality of Life in patients with head and neck cancer? A systematic review. *Oral Oncology;* 41:440-454.

Part two of the literature review: the systematic review, was undertaken to assess the following research questions:

1) What psycho-social or behavioural factors are associated with HR-QoL?

And more specifically:

2) What is the relationship between depressive symptoms and HR-QoL?

2.2.1 METHODS

2.2.1.1 Search techniques and terms

2.2.1.1.1 Databases

The following databases were searched: MEDLINE 1966-present; MEDLINE daily update; CANCERLIT 1975-2002; CINAHL 1982-present; EMBASE 1980-Present; PsycINFO 1974-present; the Institute for Scientific Information (ISI) databases of Science Citation Index Expanded (SCI-EXPANDED) 1981-present and Social Sciences Citation Index (SSCI) 1981-present via the Web of Knowledge (WOK).

2.2.1.1.2 Scanning reference lists and hand-searching

Reference lists of articles and non-systematic reviews found through database searches were also used as a literature source. In addition, the following relevant journals were hand searched to identify very recent publications (from January 2003-present) which may not have been entered onto the databases: Cancer; Head & Neck; Journal of Clinical Oncology; Laryngoscope; International Journal of Oral & Maxillofacial Surgery; British Journal of Oral &

Maxillofacial Surgery; Otolaryngology Head and Neck Surgery; Quality of Life Research, Psycho-Oncology.

2.2.1.1.3 Grey literature

Comprehensive identification of 'grey literature' is hard to achieve, however, an attempt was made to identify any peer-reviewed but unpublished work. The following database containing conference proceedings was searched: Web of Science Proceedings (formerly Index of Scientific and Technical Proceedings), also via Web of Knowledge (WOK) and any peer-reviewed dissertation abstracts listed from the searches. An attempt was also made to identify any peer-reviewed but unpublished work by asking leading researchers/clinicians in the field.

2.2.1.1.4 Search terms

Two search strategies were conducted on each database separately, based on searching subject headings (i) and a free-text search (ii), these were then combined using the boolean operator 'OR'.

i) For the subject heading search, the term 'head and neck cancer' was exploded to include the following subject index terms: neoplasms of; head and neck, hypopharyngeal, laryngeal, oropharyngeal, pharyngeal, tongue, tonsillar, esophageal, mouth, oral cavity, salivary gland, tracheal, submandibular gland and otorhinolaryngolic. This was combined with the subject heading 'Quality of life', which would also serve to include health related quality of life (HR-QoL) as a subject heading.

ii) For the free text search, terms of: Cancer$, carcino$, neoplas$, tumo?r$, "head and neck", oral, mouth$, hypopharyn$, tongue, laryn$, oropharyn$, pharyn$, tonsil$, esophag$, oesophag$, salivary, tracheal$, submandibular$, otorhinolaryn$, quality of life, qol, health state$, as text words (in title and abstract) were combined.

A more detailed breakdown of each database search can also be found in Appendix I.

2.2.1.1.5 Limitations

The searches were limited by including only literature published in the English language between the years 1980 to present and only involving human participants. The year of 1980 was considered a good cut off point due to the relative recency of literature on quality of life. All commentaries, editorials, case-reports and review articles were excluded.

2.2.1.2 Study inclusion criteria

2.2.1.2.1 Patients

Patients diagnosed with any form of malignant neoplasm (cancer) of the head or neck.

2.2.1.2.2 Outcome measures

Data were sought on HR-QoL and studies were only included if the measurement instrument was either recognised as a reliable and valid measure of QoL or if the psychometric properties of any novel measurement instruments were reported as adequate. Assessment of HR-QoL typically includes physical, psychological and social domains, therefore, measures of purely functional status were not included. Instruments such as the Hospital Anxiety and Depression Scale (HADS) and measures of disfigurement were not considered measures of HR-QoL for the purposes of this review.

2.2.1.2.3 Data extraction

Data were extracted from full-version articles using data extraction sheets (Appendix II) to ensure that data extraction was standardised.

2.2.1.2.4 Data synthesis

Disease characteristics of the patient, (ie. site and type of cancer, treatment type and outcomes) were too heterogeneous to apply formal meta-analytical pooling. Individual studies were reported separately, with their specific design features and results, in accordance with accepted guidelines (NHS Centre for Reviews and Dissemination, 2001).

2.2.1.2.5 Critical appraisal of study quality

Each of the studies was scored for quality according to seven criteria. A critical appraisal form (Appendix III) was used to score seven factors deemed most important for judging the quality of the studies. These included; the study aims or research question, study design, sample characteristics, choice of measurement instrument, statistical analysis, statistical power and validity of conclusions. Each factor was valued on a three-point scale with 0 indicating poor, 1 for adequate and 2 for good and an overall score for the study was thus calculated by summing these out of a possible total score of 14 points.

2.2.2 RESULTS

A total of 16 studies fulfilling the inclusion criteria were identified and reviewed. These were identified by reading all abstracts documented by the database search and reading the full papers of any ambiguous abstracts. The final selection of studies showed wide variation in terms of the factors that were assessed, patient sample and study design. Key data are summarized in Tables 2.2 and 2.3. Four main factors were identified in relation to HR-QoL in HNC patients. The results are discussed below under the main headings of: Personality; Social support; Satisfaction with consultation and information; and Behavioural factors. The relationship between depression and HR-QoL is discussed afterwards and includes studies that have analysed the extent to which depressive symptoms affect HR-QoL as well as vice versa.

2.2.2.1 Personality

Personality may be defined as a person's characteristics that are responsible for relatively stable patterns of feeling, thinking and behaviour (Pervin & John, 1996). There are many ways of conceptualising and measuring personality 'traits' however, few have been applied in the assessment of potential relationships between personality and QoL in HNC. Four studies were identified that attempted to examine the relationship between personality and HR-QoL. One study implemented Eysenck's early model of personality (Aarstad, Aarstad, Birkhaug, Bru, & Olofsson, 2003) whereby the personality dimensions of 'Extraversion' and 'Neuroticism' are assumed to account for a large proportion of variation in personality. Three additional studies focused on the relationship between optimism and HR-QoL (Allison, Guichard, & Gilain, 2000; Yu, Fielding, Chan, & Sham, 2001; Yu, Fielding, & Chan, 2003).

2.2.2.1.1 Neuroticism and Extraversion

A recent cross-sectional study by Aarstad et al. (Aarstad et al., 2003) demonstrated an association between personality, as measured by The Eysenck Personality Inventory (Eysenck & Eysenck, 1975), and HR-QoL in two different samples of successfully treated primary HNC patients. The patients consisted of one sample of 96 HNC patients (including primary tumour sites of: lip, tongue, salivary gland, gingiva, floor of mouth, oral cavity, oropharynx, rhinopharynx, hypopharynx, sinus, larynx and unknown primary sites) and another sample of 104 laryngectomised patients who were also members of the Norwegian Society of the Laryngectomized (NSL). This sample of laryngectomy patients is also discussed later in the review, in a study by Birkhaug et al.(Birkhaug, Aarstad, Aarstad, & Olofsson, 2002). The EORTC QLQ-C30 version 3 (Aaronson et al., 1993) and EORTC QLQ-H&N35 module (Bjordal et al., 1994) were used to measure HR-QoL, and Eysenck's Personality Inventory (EPI) (Eysenck et al., 1975) was used to measure personality traits of neuroticism and extroversion.

Table 2.2: Summary of variables studied in relation to HR-QoL

Variable	Specific component	Study
Personality	Neuroticism and extraversion	(Aarstad et al., 2003)
	Dispositional Optimism	(Allison et al., 2000; Yu et al., 2001; Yu et al., 2003)
Social support	Satisfaction with family physician support	(Mathieson, Logan-Smith, Phillips, MacPhee, & Attia, 1996)
	Extent of social contact with family, friends, neighbours	(Birkhaug et al., 2002)
Information	Satisfaction with information and consultation.	(Yu et al., 2001)
Risk Behaviour	Alcohol	(Allison, 2002; Duffy et al., 2002; Sehlen et al., 2002)
	Smoking	(Duffy et al., 2002)
Mood	Depression	(Birkhaug et al., 2002; D'Antonio et al., 1998; de Graeff et al., ; de Leeuw et al., 2000; de Leeuw et al., 2001; Duffy et al., 2002; Gritz et al., 1999; Hammerlid, Silander, Hornestam, & Sullivan, 2001b; Nordgren et al., 2003)

Aarstad et al. (2003) found that high neuroticism was associated with a lower HR-QoL in both patient samples. Specifically, neuroticism was negatively correlated with scales of global health/QoL (HNC patients $r=-0.50$, $p<0.001$; NSL patients $r=-0.33$, $p<0.01$), all general QLQ-C30 functional subscales (cluster score: HNC patients $r=-0.50$, $p<0.001$; NSL patients $r=-0.57$, $p<0.001$) and positively correlated with the majority of general QLQ-C30 symptom scales in both samples (cluster score: HNC patients $r=0.47$, $p<0.001$; NSL patients $r=0.46$, $p<0.001$) and positively correlated with the majority of H&N35 QLQ scores in the laryngectomised (NSL) sample only (cluster score: $r=0.49$, $p<0.001$). These associations were reported as stable after adjustments were made for gender, age, marital status, educational level, number of

children and level of treatment. Significant positive associations were found between extraversion scores and general health/QoL ($r=0.27, p<0.05$), Physical functioning ($r=0.20$, $p<0.05$) and Emotional functioning ($r=0.20$, $p<0.05$) in the HNC sample but only with Role functioning ($r=0.23$, $p<0.05$) in the laryngectomised sample. This finding demonstrated that higher extraversion scores were associated with better QoL functioning.

Regarding the psychometric properties of the measurement instruments, the reliability of the three HR-QoL cluster scores were found to be acceptable, with Cronbach's α values at <0.70. The EPI was subject to test-retest analysis using a small sample of n=22 HNC patients only that had previously completed the EPI during diagnostic procedures. Only the neuroticism scores ($r=0.76$, $p<0.01$) were reported to be test-retest reliable using Pearson's correlation coefficients (extraversion scores $r=0.22$, $p>0.05$).

2.2.2.1.2 Dispositional Optimism

The role of dispositional optimism on HR-QoL in HNC patients was assessed in three papers, but was the primary focus of only two (Allison et al., 2000; Yu et al., 2003).

In a prospective study by Allison et al. (2000), dispositional optimism was associated with better HR-QoL in a consecutive sample of 101 French HNC patients. The sample consisted of oral, pharyngeal and laryngeal cancer patients and measures were taken at baseline and three months following treatment. The dependent variable of HR-QoL was measured using the EORTC QLQ-C30 only and optimism was evaluated using a French version of the Life Orientation Test (LOT) (Scheier & Carver, 1985). Translation was performed using the multiple forward and backward translation protocol. The French LOT (FLOT) demonstrated internal reliability with Cronbach's $\alpha=0.66$ and external (test-retest) validity was assessed with an intra-class correlation coefficient (ICC) of $r=0.55$. Optimism scores were dichotomised around the median (score of 20) to divide the sample into 'optimists' and 'pessimists'. In

multivariate analyses of the pre-treatment data, the dichotomised LOT rating significantly predicted HR-QoL domains of: role, cognitive and emotional functioning; global HR-QoL; pain and fatigue, whilst adding treatment as another independent variable and controlling for disease site and stage. A similar result was gained from multivariate analyses conducted on three month follow-up HR-QoL data. Bivariate analyses indicated that 'optimistic' patients were more likely to report better HR-QoL than 'pessimists', however, specific results from the multivariate analyses were not reported.

In a recent repeated measures design study by Yu et al. (Yu et al., 2001), the association between satisfaction with information and QoL in 211 nasopharyngeal cancer patients was examined. In addition to these main variables of interest, trait optimism was included as part of a battery of psychosocial variables. Based on interviews, optimism was measured using a single visual analogue line of 10cms. The item stated, 'My attitude towards life is....' scored 0 for completely pessimistic to 10 for completely optimistic. HR-QoL was measured with the Chinese version of the Functional Assessment of Cancer Therapy –General Scale: FACT–G (Ch) (Yu, Fielding, Chan, & et al, 2000) which was reported as having good psychometric properties but which was not psychometrically tested within the present study.. Optimism at follow-up Time 1 (at the completion of radiotherapy but 4 months post-baseline) was initially found to be a significant predictor (β=0.14, $p<0.05$) of HR-QoL 4 months later (8 months post baseline), in addition to variables of 'satisfaction with the information provided' (β=0.20, $p<0.005$), 'worry about family' (β=-0.15, $p<0.05$), treatment (β=-0.17, $p<0.01$) and recurrence after baseline (β=-0.16, $p<0.01$). However, after adjusting for baseline QoL scores, optimism became insignificant (β=0.12, $p>0.05$).

In the same patient group (Yu et al., 2003), the mediating role of optimism between eating ability and post-radiation QoL was reported. The patient sample, data collection and measures of HR-QoL and optimism were identical to that described in their earlier study, however a

measure of eating ability was also reported. Eating ability was rated on a single 11-point item in the form of a statement, 'my eating ability is...'. 0 indicated 'very bad' and 10 indicated 'very good'. In order to test their hypothesis that optimism mediated the relationship between eating ability and QoL, a series of regression analyses were run following the procedure suggested by Baron and Kenny (Baron & Kenny, 1986) and were adjusted for baseline HR-QoL scores, family income (as a measure of economic status) and cancer stage at baseline. The results indicated that eating ability at the completion of radiotherapy was independently predictive of both optimism (β=0.24, p<0.001) and QoL 4 months later (β=0.52, p<0.001). However, this relationship was no longer significant when optimism was controlled for (β=0.11, p>0.05). These data suggest that optimism was exerting a mediating effect between the two variables.

The dataset used in the studies by Yu et al. (Yu et al., 2001; Yu et al., 2003) was collected using a mixed sampling strategy. Firstly, particular clinics were targeted and every patient was invited with the aim of recruiting at least 50%. When fewer interviewers were available, systematic sampling methods of 1 patient in 5 or 1 patient in 10 were used to achieve power targets. This mixed method lead to the inclusion of only 28% of eligible patients and thus was not a consecutive sample. In addition, data collection was a mixture of face-to-face and telephone interviews, which firstly may have lead to a selection bias by the interviewer and secondly, may have lead to concerns over the reliability of measurements due to the different method of data collection between baseline and follow-up.

2.2.2.2 Social support

Two cross-sectional studies analysed the impact of social support on HR-QoL (Birkhaug et al., 2002; Mathieson et al., 1996). In the earlier study of 45 patients by Mathieson et al. (1996), social support was measured using the Social Support Questionnaire (SSQ) (Sarason, Levine, Basham, & Sarason, 1983). The results of a stepwise regression analysis conducted using HR-QoL as the dependent variable (derived from the Functional Living Index –Cancer scale,

(FLIC)), showed four main factors predicted quality of life. Satisfaction with family physician support (partial R^2 =0.45; F=31.85; p<0.001); severity of cancer (partial R^2 =0.12; F=10.26; p<0.01); gender (partial R^2 =0.07; F=6.95; p<0.05) and type of cancer (partial R^2 =0.04; F=4.90; p<0.05) yielded a total R^2 of 0.68. Socio-economic status, marital status, time since diagnosis, history of smoking and drinking and disruption of functional activities were also entered as potential predictors. These factors were not found significant. Satisfaction with family physician support was found to be the most important contributor to patients' QoL, thus, the more satisfied the patient was, the better their QoL. Gender was also a significant predictor of QoL, whereby, women were found to be more at risk of a poorer QoL than males. In addition, the more advanced the cancer, the poorer the QoL.

In contrast, in a study by Birkhaug et al.(2002), social support was not found to be associated with QoL in 104 patients with cancer of the larynx. All of the patients had undergone surgery and more than 90% of these patients had received radiation therapy. Social support was measured using an inventory developed by Murberg et al. (Murberg, Bru, Aarsland, & Svebak, 1998). The inventory consisted of 15 questions in which the respondent was asked to indicate the extent of social contact with family, friends and neighbours. HR-QoL (as measured by the EORTC QLQ-C30 + H&N35) was collapsed into three dependent variables of: Functional and general scales; symptoms and H&N35 items. Regression analyses were adjusted for age and gender. No significant relationship was determined between HR-QoL and the amount of reported social support by family, friends and neighbours, however, specific data were not included in the paper. Depressive symptoms were also measured (discussed later).

The sample of patients in the study by Mathieson et al. (1996) included a wider range of cancer sites than normally reported in the head and neck cancer literature. For example, the 45 patients recruited included, cancer of the larynx, pharynx, glottis, skin, thyroid, tongue, sinus cavity as well as unknown primary cancers. Obviously, with such a small sample size,

controlling for site of cancer was not feasible, in addition, treatment modality was not reported in this study. Both studies were limited by their cross-sectional design and the study by Birkhaug et al. (2002) by a lack of multivariate analyses. Although, Birkhaug et al. (2002) had a larger sample in their study of 104 laryngectomy patients, their response rate was only 50%. The study by Mathieson et al. (1996) relied on an even smaller convenience sample of 45 patients.

Table 2.3: Summary of study characteristics.

Author Year (Country of study)	Study design§	Time-points of follow-up	Sample†	Dependent variables (DV)*	Psycho-social/behavioural independent variables (IV) included	Main conclusion	Overall study quality#
Aarstad et al, 2003 (Norway)	X-S	n/a	**n=96** (H&N) **mean age at study 61 yrs (sd=11); time since diag.= 4 yrs (sd=2); 78% male (T=mixed)** **n=104*** (Larynx, all S) **mean age at study 66 yrs (sd=10); time since treat.= 10 yrs (sd=7); 86% male** (*same data set as Birkhaug et al, 2002)	**n=31** HR-QoL: EORTC QLQ-C30 + H&N35 (+ 3 cluster scores as Birkhaug et al, 2002)	Personality (neuroticism, extraversion and lie scales)	Neuroticism strongly -vly assoc. with QoL in both gps. In H&N pts, extroversion +vly assoc. with QoL.	Adequate
Nordgren et al, 2003 (Sweden & Norway)	P	Diag, 1, 5 yrs post treat.	**n=86** (Larynx) **n=74 at 1yr, n=53 at 5 yrs.** 84% male; 15% S; 64% stages I/II; mean age 66 (21-88) (all RT)	**n= 1** HR-QoL: EORTC QLQ-C30 (global QoL)	Depression	Only global QoL at diag. was sig predictor of QoL 5 yrs later (depression analysed but not sig.).	Adequate
Yu et al, 2003 (China)	P	Pre-, 4 (F1) & 8 mths (F2) (n=187)	**n=211*** (nasopharynx) mean age 49.7 yrs (SD=12.2) 74% male (all RT) (*same data set as Yu et al, 2001)	**n=1** HR-QoL: FACT-G (Chinese v, sum score)	Optimism Eating ability	Optimism sig. mediated relationship between eating ability at FU1 and overall QoL at FU2. (Adjusted for: baseline QoL, family income (SES), and T stage).	Good
Allison, 2002 (Canada)	X-S	n/a	**n=191** (H&N) mean age at study 64.1 yrs (med=64;29-92); mean time since treat. = 28.1 mths (med=14;0-168); 73% male. (T=mixed)	**n=28** HR-QoL: EORTC QLQ-C30 + H&N35	Alcohol	Alcohol consumption sig. assoc. with 8 domains (age, gender, employment, site, T stage, treat + time since treat. adjusted).	Adequate
Birkhaug et al, 2002 (Norway)	X-S	n/a	**n=104** (Larynx) mean age 66 yrs (sd=10) mean time since treat. = 10yrs (sd=7), 84% male. (all S)	**n=3** HR-QoL: EORTC QLQ-C30 + H&N35: (1.functional and general scales (C30); 2. symptom scales (C30) 3. H&N35 scales)	Social support Depression	Social support not assoc. with QoL. High depression scores assoc. with reduced QoL on most measurements.	Adequate

Author Year (Country of study)	Study design§	Time-points of follow-up	Sample†	Dependent variables (DV)	Psycho-social/ behavioural independent variables (IV) included	Main conclusion	Overall study quality#
Duffy et al, 2002 (USA)	X-S	n/a	**n=81** (H&N) mean age 62 yrs (40-84); 83% male (T=n/k)	**n=12** HR-QoL: SF-36V (8 scales), HNQoL (4 scales)	Alcohol Smoking Depression	Smoking –vly assoc. with 5 SF-36V scales only. Alcohol not assoc. with HR-QoL. Depression (yes/no) – vly assoc. with all 12 HR-QoL scales (age, site and T stage adjusted).	Adequate
Sehlen et al, 2002 (Germany)	P	Start, end & 6 wks post RT	**n= 83** (H&N) median age 59 yrs (25-81); 77% male (all RT)	**n=1** HR-QoL: FACT-G (v3; sum score. Dichotomised into 'low' & 'high' QoL)	Alcohol abuse	Only ethanol abuse sig. predicted low HR-QoL 6 wks post RT. (Disease/treatment related variables and sociodemographic variables failed to prove sig.).	Poor
De Leeuw et al, 2001 (The Netherlands)	P	Pre-, 6 mths, 1,2 & 3 yrs later.	**n=197** (H&N) (n=171 at 1 yr, 139 at 2 yrs, 123 at 3 yrs); mean age at diag. 59 yrs (sd=10.6); 78% male; 80% RT; 57% (T=mixed).	**n= 4** Depression: CES-D (total score at 4 time points)	HR-QoL (Only EORTC QLQ-C30+3, subscales of: phys symptoms & phys func. + 21 phys symptom items from H&N37 module used.) Social support Coping Locus of control	Pre-treatment depr. best predictor of depr. at each time point. Adding physical symptoms to regression incr. amount of variance accounted for by 13% to 23% (at 2 yrs). Depr. symptoms and general health and tumour related symptoms pre-treat. accounted for most of the variance in depr post treat.	Good
Hammerlid et al, 2001 (Sweden)	P	Pre- & 3 yrs.	**n=232** (H&N) (n=184 at 3mths, 160 at 1yr, 133 at 3 yrs); mean age at diag. 61 yrs (18-85); 70% male (T=mixed)	**n= 3** HR-QoL: EORTC QLQ-C30 & H&N35/37, 1. Global HR-QoL, 2. emotional functioning, 3. H&N35 pain	Depression	Independent predictors of global HR-QoL at 3 yrs were physical funct. and depression at diagnosis. Pain predicted emotional funct. and emotional funct. predicted degree of pain.	Poor
Yu et al, 2001 (China)	P	Pre-, 4 (F1) & 8 mths (F2) (n=187)	**n=211** (nasopharynx) mean age 49.7 yrs (SD=12.2) 74% male (all RT)	**n=1** HR-QoL: FACT-G (Chinese v; sum score)	Satisfaction with consultation/information Satisfaction with hospital services Worry about family Anger Optimism	Satisfaction with consultation/information at F1 sig. predicted HR-QoL at F2 (β=0.21). (Adjusted for: satisfaction with services, optimism, worry about family, anger, eating ability, health, income, occupation, treatment, disease recurrence, baseline HR-QoL and T stage).	Good

Author Year (Country of study)	Study design§	Time-points of follow-up	Sample†	Dependent variables (DV)	Psycho-social/ behavioural independent variables (IV) included	Main conclusion	Overall study quality#
Allison et al, 2000 (France)	P	Pre- & 3mths post treat. (n=88)	**n=101** (H&N) mean age 58.2 yrs (SD=11.6) 93% male (T=mixed)	**n=15** HR-QoL: EORTC QLQ-C30 (5 funct scales, 1 global rating & 9 symptom scales)	Dispositional optimism	Optimism assoc. with better HR-QoL 3 mnths post-treatment. Optimism sig. predictor of all HR-QoL domains in multivariate analyses (disease site, T stage and pre-treatment HR-QoL adjusted).	Good
De Graeff et al, 2000a (The Netherlands)	P	Diag, 6mths, 1 yr.	**n=153*** (H&N) age range 29-76 yrs; 80% male. (T=mixed) (*Same dataset used for later analysis, De Leeuw et al, 2001 & De Leeuw, 2000a)	**n=16** HR-QoL: EORTC QLQ-C30 & H&N35	Depression	High level of depr. & low perf. status at baseline and combi. treat. were sig. predictors of incr. symptoms and poor funct. post-treat. Perf. status and depr. predictors of general symptoms and functioning.	Good
De Leeuw et al, 2000a (The Netherlands)	P	Diag, 6mths, 1yr.	**n=155*** (H&N) mean age= 59 yrs (sd=10.8); 79% male (T=mixed) (*Same dataset used for later analysis, De Leeuw et al, 2001 & De Graeff, 2000a)	**n= 2** Depression: CES-D (total score at 2 time points).	HR-QoL (Only EORTC QLQ-C30+3, subscales of: phys symptoms & phys func. + 21 phys symptom items from H&N37 module used.) Social support Coping Locus of control	Tumour stage, sex, general cancer related and tumour related physical symptoms and physical functioning (from HR-QoL measure) at 6 mnths explained 47% of the variance in depression at 6 mnths. Psychosocial variables at baseline explained further 12% (but this included depressive symptoms).	Good
Gritz et al, 1999 (USA)	P	Pre-, 1 & 12 mths post	**n=105** (H&N) mean age 58.4 yrs (SD=9.2) 70% male (T=mixed)	**n=6** HR-QoL: CARES-SF (5 domain scores & overall score)	Mood states: Tension-anxiety Depression- dejection Anger-hostility Confusion-bewilderment Fatigue-inertia Vigor-activity	Vigor subscale sig. predictor of overall HR-QoL score at 12 mnths. However, HR-QoL score at 1 mnth consistently predicted most of the variance in HR-QoL at 12 mnths (treatment type adjusted).	Good
D' Antonio et al, 1998 (USA)	X-S	None	**n=50** (H&N) (from 6 mths to 6 yrs post-surgery) 76% male; mean age at study=62 yrs (38-82); 74%=ND; 26% stages I/II (T=mixed)	**n=9** HR-QoL: FACT (FACT-G & FACT-HN) UW-QoL (total)	Depression	An inverse relationship was found between depr. and HR-QoL. When somatic symptoms of depression were removed, depr correlation still present.	Poor

Author Year (Country of study)	Study design§	Time-points of follow-up	Sample†	Dependent variables (DV)	Psycho-social/ behavioural independent variables (IV) included	Main conclusion	Overall study quality#
Mathieson et al, 1996 (Canada)	X-S	n/a	**n=45** (H&N) mean age =61 yrs; time since diag. range from <6 ->60 mths 73% male (T=n/k)	**n=1** HR-QoL: FLIC (composite score)	Social support (measured on 5 dimensions)	Satisfaction with 'physician support' accounted for 45% of variance in HR-QoL on own.	Adequate

§ X-S = cross-sectional study design; P=prospective study design

† RT=Radiotherapy treatment; S= surgery, T=n/k indicates treatment modality data not collected, T=mixed indicates that treatment data has been collected and is either S, R or both.

* If tests of association only were conducted, or unless specified, the HR-QoL score was tabulated under the dependent variable headed column and other variables of interest were included under the independent variable headed column for simplicity. The EORTC QLQ-C30 + H&N35 = The European Organisation for Research and Treatment of Cancer QLQ-C30 and Head and Neck module; SF-36V = Short form-36 Veterans version; HNQoL = The Head and Neck Quality of Life; FACT-G = Functional Assessment of Cancer Therapy –General Scale; CARES-SF = Cancer Rehabilitation Evaluation System –Short form; FLIC = Functional Living Index – Cancer Scale, CES-D = Centre for Epidemiologic Studies-Depression scale.

Overall quality score derived from sum of scores from seven factors each scored 0-2 (See Appendix III for factors and score definitions). Those scoring between 0-4= 'poor'; 5-10= 'adequate'; 11-14= 'good'. This score relates to how well the study answers the research question of the current review and does not necessarily relate to the original aim of the individual paper.

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2.2.2.3 Satisfaction with information and consultation

The association between satisfaction with information and QoL was assessed in a sample of patients with nasopharyngeal cancer (NPC) undergoing radiotherapy (Yu et al., 2001). In this follow-up study, Yu et al. sampled 211 newly referred patients from five hospitals in Hong Kong, China, from a cohort of 748 eligible patients. The aim of the study was to assess whether satisfaction with the information provided by physicians during consultation immediately *after* the completion of radiotherapy (but approximately 4 months after baseline), predicted QoL four months later, after appropriate adjustment for medical, demographic and psychosocial variables. Patients were interviewed (either face-to-face or by telephone) by social workers. QoL was measured by the FACT-G (Ch) (Yu et al., 2000). Predictor variables were measured using the Medical Interview Satisfaction Scale (MISS) (Wolf, Putnam, James, & Stiles, 1978), which measured patients' satisfaction with the way in which physicians provided information, and comprised cognitive, affective and behavioural subscales, including a 5-item cognitive subscale with items selected based on their relevance to NPC patients. The full nine-item cognitive scale assessed the adequacy of the physicians' explanations and ability to provide information, and the patient's understanding of the medical information. Psychosocial variables of 'patient satisfaction with hospital services' (measured with the Patient Satisfaction Scale (PSQ-9)), 'optimism' (measured using a single item visual analogue scale) and two affect scales: 'worry about family' and 'anger' (both measured using single items) were used for statistical adjustment.

Forced entry multiple regression models indicated that QoL at Time 2 (8 months after referral) was predicted by the five-item cognitive sub-scale of the MISS (β=0.21, p<0.01). This suggested that NPC patients reporting more satisfaction with the information provided approximately 1 month after the end of radiotherapy, had a better QoL 4 months later. Other variables of optimism (β=0.14, p<0.05) and worry at time 1 (β=-0.15, p<0.05), treatment (β=-0.17, p<0.01) and recurrence after baseline (β=-0.16, p<0.01), were also found to significantly

predict QoL at Time 2. All other variables were insignificant. However, when baseline QoL and stage of disease at time of diagnosis were adjusted for, the most significant predictor remained the MISS (β=0.20, p<0.01). Worry, treatment and recurrence after baseline also remained significant and all other variables, including optimism, were found to be insignificant. R^2 or R^2 adjusted values were not presented.

2.2.2.4 Behavioural factors associated with HR-QoL: Alcohol consumption and smoking

Three recent studies have investigated the relationship between alcohol intake and HR-QoL in HNC patients, with differing results. Allison (Allison, 2002), conducted a cross-sectional survey of 191 patients with either carcinoma of the oral cavity, pharynx or larynx. Dependent variables were measured using the EORTC QLQ-C30 and H&N35 module. Alcohol intake was measured with a single item question, "during the past month have you drunk alcohol on one or more occasions?" This was analysed as a dichotomous variable. The results from multivariate regression analyses showed that alcohol consumption was significantly associated with HR-QoL domains of physical functioning (p=0.005), role functioning (p=0.001), global HR-QoL (p=0.002), fatigue (p=0.02), pain (p=0.003), swallowing p=0.05), dry mouth (p=0.008) and feeling ill (p=0.03), whilst controlling for age, gender, employment status, disease site and stage, time since treatment and treatment modality. Data indicated that patients consuming at least one alcoholic drink in the past month had better HR-QoL functional scores and lower levels of symptoms than participants reporting no alcohol intake. However, the results presented in the paper lack the detail to make any more assumptions regarding these relationships.

In contrast, in a prospective study by Sehlen et al., excess alcohol consumption was found to be associated with worse HR-QoL (Sehlen et al., 2002). A sample of 83 patients with HNC (cancer sites of pharynx, tongue, floor of mouth, larynx, thyroid gland, nose, nasal sinus and

salivary glands, as well as extensive tumours) were assessed with the FACT-G questionnaire prior to radiotherapy (T1), at the end of radiotherapy (T2) and six weeks after (T3). Socio-demographic variables were measured with the Current Situation in Personal Life questionnaire, which was developed by the authors. Patients with a Karnofsky performance status score of <50 were excluded from recruitment.

Logistic regression models were used with the FACT-G sum score dichotomised into low (<70) and high HR-QoL (>70). After testing various models based on medical and socio-demographic variables, having children, current employment, alcohol abuse, level of secondary education and gender were found to account for 26% of the variance in HR-QoL at T3 (6 weeks after radiotherapy). On examination of the odds ratios, patients with no or low secondary education had a four-fold higher risk of having a low HR-QoL than patients with medium secondary education and an eight to nine-fold higher risk than patients with a high education. Male patients were at a higher risk of poor HR-QoL, as were patients without children and unemployed. However, it was found that those at highest risk of poor HR-QoL were patients reporting alcohol abuse (OR=29). The confidence intervals were not reported which, again, makes it difficult to ascertain their significance.

In contrast to both of the above studies, Duffy et al., (2002) failed to find any relationship between alcohol intake and HR-QoL (Duffy et al., 2002), although a significant relationship between nicotine and HR-QoL was found. Alcohol was measured with the Alcohol Use Disorder Identification Test (AUDIT) (Saunders, Ashland, Babor, de la Fuente, & Grant, 1993) which is a ten item screening instrument that assesses both level of alcohol intake and related problems, including hazardous drinking, alcohol abuse and dependence. Nicotine usage was measured with the Fagerstrom Test for Nicotine Dependence (FTND) (Fagerstrom, Heatherton, & Kozlowski, 1990) which is a six item questionnaire. Both of these measures were dichotomised prior to analyses into Nicotine problem (FTND score of>0 vs 0) and

Alcohol problem (AUDIT score of ≥8 vs <8). HR-QoL was measured by the SF-36V (Kazis, 1998) and HNQoL (Terrell et al., 1997).

All 12 regression models conducted, with smoking, alcohol and depression as predictor variables, and age, tumour site and stage as control variables, proved significant ($p<0.001$). Smoking was found to be negatively associated with five scales of the SF-36V; physical functioning ($p<0.05$), general health ($p<0.01$), vitality ($p<0.05$), social functioning ($p<0.05$) and role-emotional health ($p<0.05$), however, alcohol was not associated with any of the HR-QoL scales. Gender was not controlled for in the analyses.

2.2.2.5 Depressive symptoms

Nine papers were identified examining the relationship between depressive symptoms and HR-QoL. Three of these used cross-sectional designs, which make it impossible to tease out causal relationships, and the others were prospective studies with short and longer-term outcome assessments. In addition, two further prospective studies examined the relationship between depression and HR-QoL using depression as the outcome (dependent) measure. These four groups have been presented separately below.

2.2.2.5.1 Cross-sectional studies

Significant relationships between depressive symptoms and HR-QoL were found in all three of the cross-sectional studies. Duffy et al. (2000) used the Geriatric Depression Scale – Short Form (GDS-SF) (Lewinsohn, Seeley, Roberts, & Allen, 1997) to assess levels of depression in a mixed sample of 81 HNC patients and found that 44% scored higher than 3, which indicated that they had significant depressive symptoms. HR-QoL was measured using the SF-36V (Kazis, 1998) and the HNQoL (Terrell et al., 1997). All 12 multiple regression analyses conducted on the 77 patients who completed the GDS-SF (from a total of 81 patients

recruited), indicated strong negative associations between significant depressive symptoms and HR-QoL, when controlling for age, tumour site and stage, nicotine and alcohol problems.

Similarly, Birkhaug et al., (2002) also found significant relationships between HR-QoL and depression, in a sample of 104 laryngectomy patients. HR-QoL was measured using the EORTC QLQ-C30 and EORTC QLQ-H&N35. Using the 13 item version Beck Depression Inventory (BDI) (Noyes et al., 1990), 35% of patients reported either possible or probable depression. The BDI measures mood by a sum scale where 0 indicates a neutral mood and 39 indicates maximum depression. Significant negative correlations existed between all HR-QoL functional scales, global health/QoL score and depression, indicating that the lower the HR-QoL score, the higher the depression score (17 out of 20 correlations between HR-QoL symptoms and depression were significant).

An earlier study (D'Antonio et al., 1998) with 50 patients evaluated from 6 months to 6 years post-surgery also found an inverse relationship between HR-QoL, as measured by the FACT-G, FACT-HNS and the UW-QoL scales, and depression. Depression was assessed using two versions derived from the BDI; a 13-item version (which omitted somatic items) and the full 21-item version. Using the full version of the BDI, 22% of the sample demonstrated moderate to severe levels of depression (scores >13), however the range of scores were between 0 to 28 (out of a possible 73) for the full version BDI and 0 to 21 (out of a possible 39) for the 13-item version The mean value for the 13-item BDI was reported as 4, which indicated possible depression but only 9 on the 21-item version which was well within the range for non-depression. Despite this obvious discrepancy, no explanation was forwarded by the authors. Spearman's correlation coefficients showed no relationship between depression scores and demographic variables such as; age, gender, marital status, employment, religion, living situation or medical variables such as; time since diagnosis, or clinician rated disfigurement or dysfunction. However, time since most recent surgery was significantly associated with

depression ($r=0.28$, $p<0.05$). There was no relationship reported between the clinician evaluation of a patient's emotional well-being and the patient's score of emotional well-being (derived from the FACT-G) or depression. All analyses were uni-variate, therefore, no adjustments were made.

2.2.2.5.2 Prospective studies

2.2.2.5.2.1 Short-term relationship between depression and HR-QoL: ≤12 months post treatment

The relationship between depression and HR-QoL during the first year post-treatment was reported in two papers.

de Graeff et al., revealed a predictive relationship between HR-QoL and depression in a sample of 153 HNC patients (de Graeff et al., 2000b) derived from the same dataset as two other studies (de Leeuw et al., 2000; de Leeuw et al., 2001). The amount of variance in HR-QoL explained by depressive symptoms was assessed with 16 regression analyses, with HR-QoL as dependent variables. Only the EORTC QLQ-C30, EORTC QLQ-H&N35 and CES-D were used in these analyses. 26% of the sample at baseline, 24% and 22% of the sample at 6 and 12 months respectively, scored ≥16 on the CES-D, indicating possible depression.

The total amount of variance explained was slightly greater for the prediction of the EORTC QLQ-H&N35 scales than for the EORTC QLQ-C30 scales. Overall, depression, tumour stage and Karnofsky performance status were the most important predictors of HR-QoL. Depressive symptoms at baseline were the most important predictor of most of the scales of the EORTC QLQ-C30 (with the exception of physical functioning and nausea/vomiting) and some of the scales of the H&N35 (pain, sexuality and social contacts). In the multiple regression models, gender and age had only minor predictive value.

However, another 12 month prospective study (Gritz et al., 1999) involving 105 HNC patients, failed to find any relationship between depressive mood and HR-QoL. Patients were originally

recruited as part of a larger randomised controlled trial comparing two differently delivered smoking cessation programmes and as such the paper only included patients who had reported tobacco use within the last year prior to diagnosis. HR-QoL was measured using the Cancer Rehabilitation Evaluation System – Short Form (CARES-SF) (Schag, Ganz, & Heinrich, 1991) which is a generic cancer measure that yields a global score and five summary scores (physical, psychosocial, marital, sexual and medical interaction). Depressive mood was measured as part of the Profile of Mood States (POMS) scale (McNair, Lorr, & Droppleman, 1971). Six mood states have been identified from the POMS – Tension-Anxiety, Anger-Hostility, Confusion-Bewilderment, Fatigue-Inertia, Vigor-Activity and Depression-Dejection. The Depression-Dejection factor reflects sadness, guilt, emotional isolation, worthlessness and futility. The results of multivariate analyses showed that only treatment type, Vigour subscale of the POMS and 1 month HR-QoL scores, were predictive of HR-QoL at 12 months. The amount of variance in HR-QoL explained by these variables ranged from 11% to 35%.

2.2.2.5.2.2 Relationship between depression and HR-QoL: >12 months post treatment

The prospective relationship between depressive symptoms and HR-QoL, as an outcome measure, over a longer period, has been investigated in only two studies (Hammerlid et al., 2001b; Nordgren et al., 2003). Hammerlid et al. (2001) reported significant relationships between depressive symptoms and HR-QoL in 133 patients (57% of the original sample) at 3 years post-treatment. It is unclear what percentage of total eligible patients the recruited sample represented. To identify predictors of HR-QoL, three scales of; Global QoL, emotional functioning and H&N35 item of pain, were measured using the EORTC QLQ-C30 and H&N35. Depression was measured using the HADS (Zigmond & Snaith, 1983). The cut-off score for a possible case of depression is 8 to 10 (inclusive) and >10 points for probable depression. At 3 years post-treatment, only 9% of patients had possible/probable depression compared to 24% of patients just after finishing treatment.

The authors report that stepwise multiple regressions were conducted using the three HR-QoL outcomes as dependent variables. However, it is unclear whether these analyses were multiple linear regressions or logistic regressions and again, it was unclear how these dependent variables would have been dichotomised for entry into a logistic regression. Despite this, it was reported that age, gender, tumour stage, tumour site and 'selected' HR-QoL domains *measured at diagnosis* (global QoL, physical functioning scale, H&N35-swallowing, pain, fatigue, loss of appetite and feeling ill) were considered possible predictors of long-term HR-QoL. Independent predictors of global QoL 3 years post-treatment were; physical functioning ($p<0.005$) and depression at diagnosis ($p<0.05$). For emotional functioning, pain was the only predictor.

In contrast, Nordgren et al. (2003)(Nordgren et al., 2003) failed to find any relationship between baseline depression and HR-QoL 5 years after diagnosis, in a sample of patients with cancer of the larynx. The EORTC QLQ-C30 and H&N35 were used to measure HR-QoL and the HADS was used to measure depression. The percentage of patients with possible or probable depression was not reported. Regression analysis was conducted with dichotomised HR-QoL scores, however, it is unclear how many scales were regressed against or how the scales were dichotomised. Only global QoL at diagnosis was reported to be statistically significant as a predictive factor for HR-QoL 5 years after diagnosis, although it is also unclear which particular variable HR-QoL outcome was based on.

2.2.2.5.3 Depression as an outcome variable

The role of HR-QoL in predicting depression was examined in 2 papers based on the same dataset. De Leeuw et al. (2000) collected data on 155 HNC patients at 6 and 12 months following treatment, in order to assess whether pre-treatment factors, including HR-QoL, could be used to predict depression at these time points. HR-QoL was represented by three scales of: general cancer related physical symptoms derived from 12 items from the EORTC

QLQ-C30+3, the Physical Functioning scale from the EORTC QLQ-C30+3 and head and neck tumour specific and treatment related physical symptoms derived from the 21 items of the EORTC QLQ-H&N37 (Bjordal et al., 1999). Social support, coping and locus of control were also measured as predictive variables. Different types of social support were assessed with the Social Support List Interactions (van Sonderen, 1991), items from the Inventory of Socially Supportive Behaviours (Barrera, Sandler, & Ramsey, 1981), the Social Provisions Scale (Cutrona & Russel, 1987) and separate items asking about the extent of formal and informal networks. Coping was measured with the short version of the Utrecht Coping List (Schreurs, 1997) and locus of control was measured with the short version of the Cancer Locus of Control Scale (Watson, Pruyn, Greer, & van den Borne, 1990).

Stepwise multiple regressions were conducted to predict depression at 6 and 12 months post-treatment, entering tumour stage, age, sex, depressive symptoms at baseline, coping, cancer locus of control, support, the extent of social network, openness to discuss cancer in family, HR-QoL - general cancer related physical symptoms, HR-QoL - tumour and treatment related physical symptoms and HR-QoL - Physical Functioning. The total amount of variance explained in depressive symptoms was 66% at 6 months and 52% at 12 months. In addition to tumour stage (R^2 change=0.04) and sex (R^2 change=0.03), current HR-QoL - general cancer related symptoms (R^2 change=0.41), tumour related symptoms (R^2 change=0.03) and physical functioning (R^2 change=0.03) explained 47% of the variance at 6 months. Psychosocial variables measured prior to treatment explained an additional 12% of the variance (depressive symptoms, avoidance coping and the extent of formal social network). However, it is clear that most of this variance was from depressive symptoms (R^2 change=0.09). At 12 months, 14% of the 52% of variance in depression was accounted for by baseline psychological measures. Depressive symptoms accounted for half of the variance (R^2 change=0.07).

Unsurprisingly, a similar relationship also emerged from another study by de Leeuw et al. (2001), reporting a slightly higher recruitment rate of 197 patients with 6 months post-treatment data and 171 patients with 12 months post-treatment data. (See de Leeuw et al, 2000) for description of methodology, measurement instruments and statistical analyses.) Again, it was demonstrated that depressive symptoms prior to treatment were the best predictor of depressive symptoms at each time point (with R^2 change=0.32 at 6 months and R^2 change=0.18 at 12 months). The three measures of current HR-QoL – general health and tumour related symptoms and physical functioning, accounted for only 19% of the variance at 6 months and 14% of the variance at 12 months. Stepwise multiple regressions were also conducted to predict depression at 2 years and 3 years post-treatment, entering the same variables as described previously. Data from 139 patients at 2 years post treatment and 123 patients at 3 years post-treatment, indicated that depression at those time points was mostly explained by baseline (pre-treatment) depression. HR-QoL could explain a further 20% approximately. Patients who had a recurrence during this time-period were not excluded from these analyses.

2.2.3 LIMITATIONS

2.2.3.1 Study design and quality

The majority of studies included in this review are limited by methodological and statistical problems or missing data. However, seven of the studies (Table 2.3) included in this report attracted the highest 'quality' score of 'good' (scores of at least 11 out of 14) when critically appraised according to the criteria (Appendix III). Three studies were deemed to be of a 'poor' quality (scores of between 0 and 4). The majority of studies did not forward any specific hypotheses for testing and all of the studies lacked any hypothetical or theoretical framework on which to base their research questions.

The studies varied in sample sizes and response rates, ranging from sample sizes of 45 (Mathieson et al., 1996) to 232 (Hammerlid et al., 2001b). Response rates for the studies ranged from 28% of the original number of patients eligible for inclusion (Yu et al., 2001; Yu et al., 2003) to 99% (Allison et al., 2000), however, many of these were based on convenience samples and in many studies the exact number of patients eligible for inclusion at the time of the study has not been reported, therefore, the response rates cannot be ascertained. This limits the ability to generalise from these studies.

2.2.3.2 Health-Related Quality of Life as an outcome measure

The majority of the studies used the EORTC QLQ-C30 & HN35 to assess HR-QoL. However, many different dependent (or outcome) variables were selected to measure relationships between variables. The lack of concordance between results may have been due in part to using different measures of HR-QoL or using different subscales of the same measure. For example Mathieson et al. (1996) used a composite score from a general measure of HR-QoL in cancer patients and Birkhaug et al. (2002) used both general cancer and head and neck cancer specific scales in their assessment of the relationship between HR-QoL and social support. In addition, studies used different methods to collect data. For example, data were collected from mail-outs, face-to-face interviews, telephone interviews and by different members of staff, for example, trained social workers, researchers, consultants, nurses etc, all of which may have affected the response.

2.2.3.3 Statistical limitations

Few studies included any analyses of the psychometric properties of the measurement instruments with their own samples, although most used standardised instruments. In general the level of statistical detail provided proved poor. In many cases it was difficult to ascertain how results had been statistically derived from the data. Many of the studies relied on uni-variate analyses between variables and many of the regression analyses poorly controlled for

factors already known in the literature to affect HR-QoL (e.g. various socio-demographic and medical/treatment factors). HR-QoL at baseline was not always adequately controlled for when analysing data from prospective studies.

It was unclear whether much of the data published met assumptions for parametric testing and the lack of detail made it difficult to determine whether variables entered into regression models were statistically appropriate. Authors rarely mentioned whether skewed data had been transformed before analyses. Similarly, there was a general lack of detail regarding missing data and how this was dealt with before analyses. Despite the small sample sizes generally recruited in the field of head and neck cancer, few of the studies reported actual power calculations or provided comment about the power of study based on their method of analyses.

2.2.3.4 Determining causality

Many of the studies described in this review have been cross-sectional in design.. This may be sufficient to determine relationships, however, causality cannot be determined and therefore the variables under study cannot be assumed to be 'predictive' of HR-QoL.

2.2.4 DISCUSSION

Health related quality of life is now considered an important patient centred outcome variable following treatment for head and neck cancer. This has lead to a dramatic increase in the number of studies incorporating assessments of HR-QoL. Despite this increase in interest, the majority of studies investigating HR-QoL in this population have mainly been aimed at comparing the impact of different treatment modalities and have therefore only commented upon the effects of treatment and disease related variables. This has resulted in knowledge about the effects of disease site and treatment on HR-QoL, however, few studies have attempted to explore the role of non-clinical variables in relation to impact on HR-QoL.

The limited data regarding the role of personality traits on reported HR-QoL indicated significant predictive and associative relationships. All four studies examining trait characteristics of either neuroticism/ extraversion or optimism were considered 'adequate' or 'good' in quality (Aarstad et al., 2003; Allison et al., 2000; Yu et al., 2001; Yu et al., 2003). Results demonstrated that the higher the extraversion or optimism score of the patient, the better they rated their HR-QoL. In contrast, patients scoring highly for neuroticism were more likely to have a low HR-QoL. Personality is thought to influence health outcomes either directly or indirectly through a number of mechanisms. It has been suggested that psychological constructs such as 'optimism' and 'neuroticism' may actually reflect negative affectivity (NA) (Clark & Watson, 1991). High trait NA individuals are characterized by the tendency to experience a range of distressing negative emotions such as anxiety and depression and studies have also shown that high NA is associated with more symptom reporting across a wide range of illnesses, regardless of objective physical illness (Petrie, Moss-Morris, Grey, & Shaw, 2004; Watson & Pennebaker, 1989). Another pathway between personality and health outcome has been investigated by examining coping styles. Dispositional optimism has been found to correlate positively with problem-focused coping, the positive reinterpretation of a problem and the attempt to accept the reality of situations that are perceived to be uncontrollable (Scheier et al., 1985). Coping may be an important mediator between personality and outcome and thus may be more open to psychological intervention than directly targeting relatively stable personality traits.

The role of social support on HR-QoL is less clear. Of the two 'adequately' rated cross-sectional studies, one study failed to find any relationship between the 'extent of social support from family, friends and neighbours' and HR-QoL (Birkhaug et al., 2002), whereas, another study demonstrated that 'satisfaction with physician support' accounted for 45% of the variance in HR-QoL (Mathieson et al., 1996). The 'support' assessed in these two instances illustrates not only the wide differences in underlying construct between different types of

social support measure but of the subsequent implications that arise from employing different types of support measure. Interestingly, the study finding no relationship between level of support and HR-QoL involved laryngectomy patients who may have more complex issues involving communication, social support needs and subsequent HR-QoL. The direct beneficial effect of social support on outcome appears paradoxical in the literature. Social support is a complex interactive construct, which may only be effective when matched with the patients needs. Potential forms of support have been described (House & Kahn, 1985) as emotional, appraisal, informational and instrumental.

Schreurs and de Ridder (1997) have described four ways of relating social support to coping: as a coping strategy, as a coping resource, as a consequence of coping and fully integrated into a coping process of a social system (Schreurs & de Ridder, 1997). Evidence suggests that social support is differentially related to coping style and personality. Studies with breast cancer patients have shown that important support lies in the spouse's reactions to cancer, and interpretations of spousal support and coping style relate to the coping style adopted by the patient (Ben-Zur, Gilbar, & Lev, 2001). Other studies also confirm that it is the perceived quality of the social support that affect outcomes such as well-being and depression (Martire, Schulz, Wrosch, & Newsom, 2003). It is these components and categories of support which need to be explored in more detail in future work in order to have a clearer understanding of their possible effects on QoL.

Alcohol and nicotine usage was found to be associated with HR-QoL in two ways. An 'adequately' rated cross-sectional study by Allison (2002), found having had at least one alcoholic drink in the past month (post-treatment) was associated with higher levels of HR-QoL. This may have been due to better functional abilities in swallowing and drinking rather than alcohol influencing HR-QoL. In a 'poorly' rated study by Sehlen et al. (2002), excess alcohol was associated with a worse HR-QoL, which may have been representative of worse

disease and an addiction to alcohol. Similarly, Duffy et al. (2002), found a negative relationship between nicotine dependence and HR-QoL, demonstrating that those with a high dependence to nicotine reported worse HR-QoL. The relationship between behavioural factors such as smoking and drinking alcohol and HR-QoL is confounded by the severity of symptoms the patient is experiencing. The scope for providing support and intervention in treating addictions such as these for particular at risk patients would be beneficial not only in terms of an individual's QoL but also to limit the chance of cancer recurrence in the future, as alcohol and tobacco are well known aetiological agents of HNC.

A fairly inconsistent picture emerges from the literature regarding the relationship between depressive symptoms and HR-QoL. Of the nine studies included in this review, seven reported significant relationships between depression and HR-QoL (Birkhaug et al., 2002; D'Antonio et al., 1998; de Graeff et al., 2000a; de Leeuw et al., 2000; de Leeuw et al., 2001; Duffy et al., 2002; Hammerlid et al., 2001b), despite the wide range of depression measures applied and the range in quality ratings of the studies. However, three of the studies reporting associations were cross-sectional in design and analyses were uni-variate. Therefore direction of causation is unknown. Regarding depression as a predictor of HR-QoL, the results appear inconclusive as 2 out of 4 of the studies failed to find a significant relationship in either the short-term or the longer term. Of the two studies examining the role of HR-QoL on depression, it was found that although significant relationships existed, depression at baseline was a far better predictor of depression than current HR-QoL. These last two studies were rated highly as 'good', but were actually based on the same data set and similar analyses and, therefore, should not be taken as providing 'double' the support for this particular finding.

Of the two studies that failed to find significant relationships alternative explanations can be put forward. Although the study by Gritz et al. (1999) was considered 'good', the contradictory finding may have been due to the measurement instrument. The factor of 'depression-

dejection' may not have been tapping the same underlying constructs as more widely used measures of depressive symptoms, as the POMS is usually used as a measure of transient mood state in clinical settings. However, an 'adequately' rated study by Nordgren et al. (2003) also failed to find any significant relationship. It is not surprising that depression is related to HR-QoL, however, it is difficult to ascertain which has the overriding influence on the other as the relationship between depression and HR-QoL is complex and dynamic. The lack of consistency regarding the relationship between depression and other outcomes, not just HR-QoL, reflects a fundamental problem in all areas of the literature and not just HNC. This discrepancy also illustrates that lower HR-QoL may not necessarily lead to depressive symptoms or conversely that those who are depressed may have a relatively good HR-QoL compared to others. The underlying mechanism for this inconsistency may be due to adaptive or non-adaptive processes, such as 'burnout' as a result of long periods of stress as suggested by Rapoport et al (Rapoport, Kreitler, Chaitchik, Algor, & Weissler, 1993) or adjustment to the illness and threat (de Graeff et al., 2000b), both of which may be related to mediational factors such as coping or effectiveness of support networks as mentioned previously. The relationship between physical symptoms/impairment and depression is far from understood. Further research is needed to unravel these relationships.

This systematic review highlights the relative lack of research exploring the influence of psycho-social factors on HR-QoL in HNC and demonstrates the need for more robust and theoretically based studies in this area. As the clinical disease and treatment related factors are not open to alteration, the psychological reaction to these factors may be modified. Further research may elucidate which psychological factors would be best targeted for psychological intervention, either for at risk groups or individuals at risk of poor outcome.

The following chapter provides a critical overview of additional psychological factors that have been established as influential on outcomes, such as quality of life and mood, in other illness

groups. This was conducted in order to inform the selection of appropriate variables for the main study, based on the wider literature. The chapter also introduces the theoretical context to the subsequent studies presented in the thesis, in terms of a self-regulatory framework which has not been widely applied in the field of HNC previously, and discusses the processes by which psychological factors could influence perceptions of QoL.

CHAPTER 3

APPLYING A SELF-REGULATORY FRAMEWORK TO EXPLORE ADAPTATION AND OUTCOME IN CANCER: PSYCHOLOGICAL DETERMINANTS

3.1 INTRODUCTION

The studies discussed in Chapter 2 demonstrate two points. Firstly, that not much is known about the more subjective and patient centred aspects of QoL in patients with head and neck cancer, and secondly, that there is inadequate knowledge of the psychological determinants of outcomes such as quality of life or depression.

Models typically used in health psychology, such as social cognition models (SCM), provide good theoretical frameworks for examining variables that could be influential in explaining outcomes, and for providing a context for the underlying processes. The importance of applying a theoretical model to research lies in the ability to then identify appropriate targets for intervention based on sound theoretical underpinnings.

SCM's such as the Health Belief Model (Rosenstock, 1974), the Theory of Planned Behaviour (Ajzen, 1985) and the Health Action Process Approach (Schwarzer, 1992) are all theoretical approaches to the understanding of health related behaviours. However, the main criticism is that many of these models do not address the dynamic nature of how people make judgements, such as coping and quality of life, based on a particular health threat.

One such model that is commonly applied in the investigation of patient outcomes in chronic illness is the Self-Regulatory Model proposed by Leventhal and colleagues (Leventhal, Meyer, & Nerenz, 1980). The central proposition of this theory is that the cognitions (or

representations)[1] patients have about their illness are the key to understanding patient outcomes based on judgements (such as QoL and mood). This model could be useful in explaining variation in outcomes between patients that cannot be explained by either socio-demographic, or disease and treatment related factors.

The following chapter begins with an overview of Leventhal's Self-Regulatory Model (SRM) and the key explanatory factors or process variables central to the theory. A review of studies examining the relationship between illness cognitions and outcome in patients with a variety of illnesses are discussed with special reference to any studies involving cancer patients.

This section is followed by a discussion of how other psychological predictors of outcome, such as the role of expectations, could be related to judgements of outcome from the perspective of the SRM.

The third section briefly introduces a specific phenomenon inherent in outcome studies such as QoL research, which is known as 'response shift'. Response shift is of particular importance when individuals undergo a change in health state, and refers to the dynamic process of changing internal standards, values or conceptualisation of QoL. This adaptational process has important implications for the measurement and interpretation of QoL scores and is described and discussed in relation to longitudinal outcome studies.

Chapter 3 closes with suggested implications of the review to the present series of studies, and thus establishes the key objectives of the thesis based on the three literature reviews presented in both chapters 2 and 3.

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[1] A number of other terms are often used in the literature: illness cognitions, perceptions, schemata and beliefs. These terms are considered to be synonyms of illness representations (Scharloo & Kaptein, 1997) and are used interchangeably throughout the thesis in reference to how people think about their illness and treatment.

3.2 THE SELF-REGULATORY MODEL: AN OVERVIEW

The Self-Regulatory Model (Leventhal, Nerenz, & Steele, 1984), originally and alternatively referred to as the 'Common-Sense' Model (Leventhal et al., 1980), has provided a theoretical basis for the understanding of how cognitive factors influence coping behaviours and outcomes in illness. The SRM was developed to identify and predict how individuals represent and respond to a health threat.

Leventhal & Nerenz (1985) originally based their approach to the study of cognition on a few basic assumptions that had been noted some time previously. Firstly, that individuals are active problem solvers, not passive responders (Kelly, 1955), and that behaviour is directed by perceptions and interpretations of specific situational stimuli (Lewin, 1935). This lead to the observation that experience and behaviour are not new with each stimulus, but reflect an interaction between external events and a personal knowledge base consisting of both cognitive and emotional schemata (Leventhal, 1980; Leventhal, 1984). In addition, there is a time-frame to the construction of a representation of, and response to a health threat. As the representation is constantly updated with the processing of new information, the proposed theory can be considered 'dynamic', to the extent that individuals are engaged in a constant process of interpreting and evaluating the health threat (Leventhal & Nerenz, 1985). The last important assumption is that although successive episodes will reflect prior episodes, unique situational factors and variation in individuals schemata will lead to wide variation in the common-sense models that individuals generate. This has lead to the critique that prediction over situations and time is essentially problematic (Nelson, 1983).

The construction of a personal common sense model to a health threat is the product of an underlying control system which can be divided into three broad processes which are shown in figure 3.1. Firstly, the cognitive and emotional representations of the health threat are constructed. These representations are a result of the individual's interpretation of the health

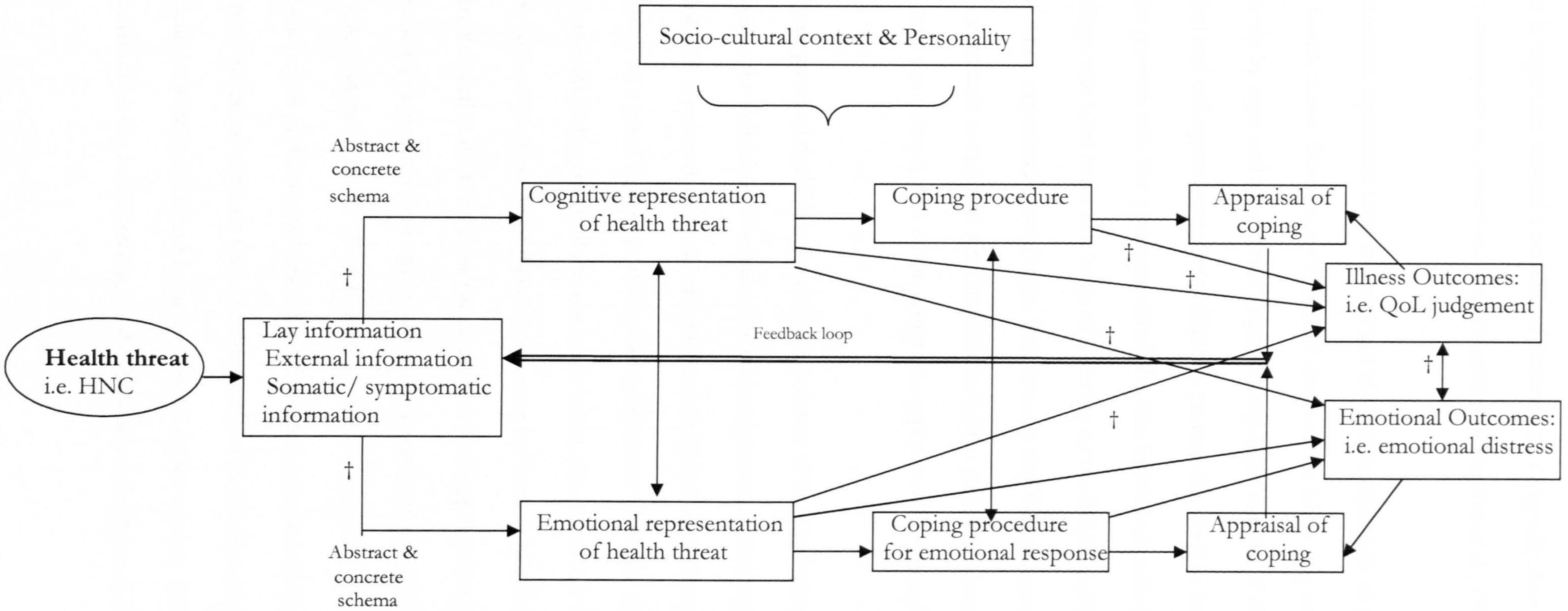
threat and can be a result of internal cues, for example, symptoms, and/or external cues such as sources of information. Secondly, an action plan is developed. The coping strategy used is perceived by the individual to be appropriate to the representation of the problem. The third stage is the process of coping appraisal. This is a process of evaluating the effectiveness of the coping strategy on the outcome or goal. Each of these steps or processes is examined in more detail below, but the two key attributes of the SRM are that these three stages occur in parallel (the SRM is a 'parallel processing' model) on both an emotional and cognitive level (as shown in figure 3.1), and that the interaction between each level is 'dynamic', meaning that each component is influenced by a process of feedback. Thus, representations of the health threat and coping strategies are subject to adjustment. A core assumption of this self-regulatory system is that individuals are attempting to make sense of and minimise threats to 'self' and their self-goals. It is in these ways that the system can be considered self-regulatory.

3.2.1 Cognitive and emotional representations of a health threat

The SRM proposes that individuals form beliefs about their illness based on both abstract and concrete sources of information available to them (see figure 3.1). This assists them in making sense of the threat and deciding on a method to deal with the problem. However, it is the interpretation of the information (the resulting belief) that decides the management of the problem e.g. seeking help or adhering to medical intervention, etc (Bishop & Converse, 1986).

Leventhal and colleagues suggest that beliefs are potentially formed by three sources of information (Leventhal et al., 1980; Leventhal et al., 1984). The first source being the general pool of 'lay' information that the individual has previously assimilated. The second source is derived externally from friends, family and authoritative resources. The third source of information is the current experience of the illness, such as somatic experiences and symptoms. If the illness has been experienced before, previous experience of symptoms and coping will also be influential in forming an interpretation or belief about the current illness.

Figure 3.1: Schematic representation of Leventhal et al., (1984) Self-Regulation Model, with the influence of process variables on outcomes added



Extensive qualitative and quantitative research has established that the content of illness representations is organised around a number of dimensions. Originally, four main themes of: illness identity, consequences, causes and were identified (Leventhal et al., 1980).

The *identity* dimension represents both concrete and abstract components of providing an identity to the health threat. Illnesses are identified abstractly by labels (e.g. cancer, heart attack etc) and concretely by signs and symptoms. Together they result in a belief about the likely illness. Leventhal and colleagues have shown that this process can work in both ways as proposed by the *symmetry rule*. The symmetry rule holds that individuals will, 1) seek symptoms when given a diagnostic label (such as a name of a disease or condition), and 2) seek a diagnostic label when experiencing symptoms. This ensures that there is consistency between internal states (or somatic states) and the interpretation of the problem. Most measures of illness identity only use a simple sum of the symptoms experienced as part of the illness.

The perceived *consequences* of the illness are assessed in terms of the physical, social and economic impact to the individual. The *cause* dimension represents beliefs regarding the likely cause of the illness. A number of key factors have been identified from research using different illness groups, such as: a genetic predisposition, biological causes (immune system, germs and viruses), environmental pathogens (pollution or toxic waste), the individuals own behaviour (risk behaviours such as smoking, poor diet etc), stress or bad luck. It has been noted that there can be considerable overlap between these causal constructs (Hagger & Orbell, 2003) and some researchers have used single item measures to ensure only one main causal belief is interpreted (Kemp, Morley, & Anderson, 1999). Many researchers choose not to include a measure of cause due to the inherent problems with meaningful interpretation and analysis. The *timeline* of the illness refers to the perceived time frame of the course of the illness and time scale of symptoms. Recently, *timeline* beliefs have been considered as two separate dimensions: providing information on the beliefs relating to the *chronicity* of the illness, in addition to beliefs

about the *cyclical* nature of the illness (Moss-Morris et al., 2002). In 1983, *cure/control* beliefs were included (Lau & Hartman, 1983), which refers to beliefs regarding the potential for cure or control of the illness. Recently, this dimension was also considered as two distinct constructs relating to personal control and self-efficacy beliefs and the other related to beliefs regarding the ability of the treatment to control or cure the illness (Moss-Morris et al., 2002).

The emotional representation of the health threat is also an important component of the SRM. The model proposes a parallel system of developing both cognitive representations and emotional responses to an illness (figure 3.1). Each of these representations then lead to respective problem-based and emotion-focused coping procedures (Moss-Morris et al., 2002). In addition, it is plausible that emotional representations affect the emotional outcome of the self-regulatory process.

The extent to which an individual's illness representation provides a coherent understanding of the overall illness has been investigated recently. The illness coherence subscale is now included in assessments, however, this 'meta-cognition' refers to the extent to which an individual considers their illness representations are coherent rather than a separate belief as such (Moss-Morris et al., 2002). Common methods of assessing cognitive and emotional representations are evaluated in section 3.2.4

The role of personality and cultural contexts has also been acknowledged as potentially influential in the formation of representations (Diefenbach & Leventhal, 1996; Landrine & Klonoff, 1992).

3.2.2 Coping procedure

The coping behaviours or strategies employed by the individual in response to their illness and representations are important components of the SRM. Checklists of measures are usually used

to assess specific types of coping processes and again, due to the parallel processing of cognitive and emotional representations about the health threat, coping can be considered either cognitively based or emotion-focused. Using coping scales to assess coping does not typically provide a specific idea of the coping process but are useful for giving a general idea of the strategies used at a given time. However, it has long been asserted by Leventhal and colleagues that the way that coping is measured (i.e. using checklists) could be problematic and using the terminology of 'procedure' is preferable to the term 'coping', as it helps to avoid the conceptual pitfalls underlying much of coping research (Leventhal et al., 1997). Nevertheless, the term 'coping' is used throughout the thesis to maintain continuity with the literature with the caveat that the above is taken into account.

It must also not be overlooked, that coping or procedures for coping, occur in the context of the situation.

3.2.3 Appraisal of coping procedure

The process of appraisal also demonstrates the dynamic aspect of the SRM. Appraisal occurs when the individual evaluates the effectiveness of the coping strategy being employed, on the outcome or goal. According to whether the appraisal is considered effective on the goal, a feedback system allows for the reinterpretation of symptoms and thus the modification of the cognitive and emotional representation and a different coping strategy may then be tried. Assessment of the appraisal process itself is not common and may be best achieved through open-ended interviewing.

3.2.4 Measurement of illness representations

A number of standardised questionnaires have been developed to assess Leventhal et al.'s (1980) theoretically derived domains discussed in section 3.2.1, best known amongst these are the Illness Perception Questionnaire (IPQ) (Weinman, Petrie, Moss-Morris, & Horne, 1996),

the revised Illness Perception Questionnaire (IPQ-R) (Moss-Morris et al., 2002), the Brief Illness Perceptions Questionnaire (BIPQ) (Broadbent, Petrie, Main, & Weinman, 2005) and the Implicit Models of Illness Questionnaire (IMIQ) (Turk, Rudy, & Salovey, 1986).

Alternatively, a quantity of the research on illness representations has been based on qualitative methods. For example, the Personal Models of Diabetes Interview (PMDI) (Hampson, Glasgow, & Toobert, 1990) assesses constructs such as beliefs about the seriousness of diabetes, treatment effectiveness, cause and symptoms, and, similarly for osteoarthritis with the Personal Model of Osteoarthritis Interview (Hampson, Glasgow, & Zeiss, 1994). Some studies have reported the use of open-ended interviews to investigate beliefs (Lau, Bernard, & Hartman, 1989) and some have used more structured approaches to interviewing (Heijmans, 1998; Heijmans, 1999; Heijmans & de Ridder, 1999; Heijmans & de Ridder, 2005), in a wide range of illness groups.

3.2.5. Empirical evidence of the relationship between components of the SRM

The SRM as a whole is difficult to empirically test due to its complexity as a feedback system. However, many studies have sought to answer research questions based on key facets of the SRM, such as the relationships between illness representations and coping behaviours, or between illness representations and outcomes. Many studies have been cross-sectional 'snapshots' of relationships at a given time, and therefore cannot provide any indication of the direction of the associations. Sections 3.2.5 to 3.2.6 provide a discussion of a selection of the literature to highlight the main relationships found between components of the SRM. It is beyond the scope of this thesis to include all of the empirical evidence to date.

3.2.5.1 Illness representations and coping

Many studies have examined coping behaviours in relation to the SRM overall, in particular the influence of coping on outcomes (Groarke, Curtis, Coughlan, & Gsel, 2004; Scharloo et al., 2000; Sharpe, Sensky, & Allard, 2001; Whitmarsh, Koutantji, & Sidell, 2003), however few

studies have been published which assess the relationship between coping and illness beliefs. Two such studies published in 2002 investigated the direct associations between illness representations and coping, and also in relation to outcome (Helder et al., 2002; Rutter & Rutter, 2002). Helder et al, (2002) investigated the role of illness perceptions and coping mechanisms on well-being in a cross-sectional study of 77 patients with Huntington's disease (HD). Using the IPQ, The COPE Inventory (Carver, Scheier, & Weintraub, 1989), and the MOS SF-36 (Ware & Sherbourne, 1992) (perceptions in relation to outcomes are described in more detail in section 3.2.6), patient beliefs were found to be related to specific coping subscales. Illness identity scores were found to be positively correlated with 'mental disengagement', whereas beliefs regarding the duration of HD were negatively correlated. These results indicated that having a strong illness identity and believing that the illness would only last a short time were associated with mental disengagement. Beliefs regarding a possible cure were positively associated with seeking emotional social support, and also mental disengagement. Beliefs regarding the controllability of HD were positively associated with 'positive reinterpretation' of the situation and 'growth' (Helder et al., 2002). The cross-sectional design of this study, however, makes it impossible to determine the direction of associations between components of the SRM.

In another cross-sectional study by Rutter and Rutter (2002), the IPQ and The COPE were again used to assess the illness representations and coping strategies of 209 patients with irritable bowel syndrome (IBS). This study was intended to examine whether representation components could predict outcome (QoL), and to evaluate whether coping was a mediating variable. Uni-variate analyses showed that individuals who expected their illness to last a long time were more accepting of their IBS. Strong perceptions of the negative consequences of the disease were associated with the use of restraint coping, venting emotions and mental and behavioural disengagement. Stronger cure/control beliefs were associated with more active coping, planning and positive reinterpretation. Path analyses demonstrated that coping

mediated the associations between representations and outcome, which indicates some support for Leventhal's SRM. However, similar to much of the work in this area, this study neglected to take into account the emotional branch of the SRM and chose to focus only on cognitive beliefs. It is likely that the emotional response to IBS would equally contribute to coping behaviour and outcome. Again, due to the cross-sectional design, this study does little to provide any enlightenment as to the causal direction of associations between components, despite the model's premise that the relationship is causal.

The main difficulty with determining causality between illness representations and coping is that researchers have used many different methods to assess coping procedures. Some have used behavioural markers of coping, for example, attendance at clinics or a general practitioner (Hampson et al., 1994; Lau et al., 1989), adherence to treatment (Horne & Weinman, 2002), levels of self-care (Heijmans et al., 1999) or standardised coping checklists such as The COPE or the Utrecht Coping Questionnaire (Schreurs, Willige, Tellegen, & Brosschot, 1993).

A clearer picture has emerged from recent work that classified studies into seven main categories based on the coping behaviour or strategy used, and reported associations between illness beliefs and coping using meta-analytic techniques (Hagger & Orbell, 2003). The seven coping categories were as follows: Avoidance/denial; cognitive reappraisal; number of visits to the doctor; expressing emotion; problem focused coping – generic; problem focused coping – specific; and seeking social support. An important finding revealed from the meta-analysis, was that perceived controllability was related to active coping and positive reappraisal. Patients who believe their illness to be controllable were more likely to use cognitive strategies to help them reappraise their situation. This process of reappraisal is further discussed in terms of 'response shift' in section 3.4.

Seeking social support was not found to be consistently related to illness beliefs in the meta-analysis. This may have been an artefact of the generalised nature of measures of social support used in the studies. Perceptions of identity and consequence were found to be related to avoidance/ denial and expressing emotions. Timeline was most strongly related to cognitive reappraisal and also with avoidance/denial (Hagger et al., 2003).

Although attempts have been made to measure coping on a more behavioural level, i.e. specific problem focused strategies and measuring doctors' visits, the majority of the studies still rely on previously validated questionnaires. Measures such as these have been criticised in terms of their general nature and their failure to account for individual differences in coping styles and the personal goals of coping strategies used (Coyne & Racioppo, 2000). More importantly, they do not capture the relationship between the coping strategy employed and the reason for it based on SRM specifications. For example, the 'if-then' rule suggests that a person's beliefs about the likely cause of the condition will be influential in deciding on the appropriate coping strategy to use.

3.2.5.2 The relationship between treatment perceptions and components of the SRM

Based on Leventhal's self-regulatory model, it would seem plausible that any coping procedures and subsequent outcome could also be influenced by the perceptions held about their treatment. In order to maintain coherence between concrete symptoms, beliefs, coping, and outcome, the patient as 'active problem solver' seeks to close the perceived gap between current health status and goal state. Whether the proposed treatment makes sense in light of these beliefs will influence the outcome (whether this is in terms of well-being or adherence to treatment). An extended version of the SRM has been proposed by Horne and colleagues, which stipulates that self-regulating patients will *'not just have their own ideas about the illness, but also about the treatment being offered'* (Horne et al., 2002). This extended model was originally used to

provide an explanation for adherence to medication, however, treatment beliefs could equally be important in the perception of outcomes, such as QoL.

Research has identified two important treatment constructs: beliefs about the *necessity* of treatment for maintaining or improving health, and *concerns* regarding the potential harmful effects of treatment. A study of asthma patient's adherence to preventer medication concluded that significant relations existed between illness perceptions and treatment beliefs (Horne et al., 2002). Patient's models of their illness and treatment were noted to interact in a logical way, for example, patients who believed their asthma to be a chronic condition with negative consequences, were more likely to perceive their preventer medication to be necessary to their health. This provided preliminary support that the amount of variation in outcome (in this case adherence to treatment) explained by the illness perceptions framework could be enhanced by including patient's beliefs about the treatment (Horne, 1997; Horne & Weinman, 1998).

3.2.6 Quality of life as an outcome of a self-regulatory process

The use of QoL measures is abundant in outcome studies involving patients and, as shown in chapter 2, HNC is no exception. However, the cognitive processes underlying its judgement have largely been neglected. Establishing predictors of QoL could be useful for targeting interventions towards those patients who are most likely to experience poor QoL.

Leventhal and Colman (1997) argue that by exclusively focusing on QoL as an explicit outcome, the view of QoL as a subjective judgement of life quality and not just a marker of physical or cognitive function or mood, is obscured. They propose a framework for a process model which emphasises firstly, that QoL should be reflected by functioning within a number of life domains and the value placed on these domains, and secondly, that judgements are affected by many contextual factors. The context for this process model is the person's

cognitive representation and emotional response to the disease and treatment (Leventhal & Colman, 1997).

3.2.6.1 Measures of function versus quality of life

Researchers have recently acknowledged that the majority of QoL measures tend to assess symptoms and functioning and ignore the importance placed on them (Hyland, 1992; O'Boyle, McGee, & Joyce, 1994; Schwartz & Sprangers, 1999). Whether this is on an emotional, physical or cognitive basis, and general or specific to the illness, instruments essentially assess symptoms and not QoL as a complex construct. In addition, treatment side-effects or functional impairments may mean different things to different people according to the views they hold about them. For example, the toxic side-effects of chemotherapy experienced by breast cancer patients may be considered more threatening to QoL than the disease itself, whereas, the side-effects may be viewed by some people as positive indictors of the treatment's effectiveness in controlling the cancer (Nerenz, Leventhal, Love, & Ringler, 1984). Leventhal & Colman (1997) stress that, *'the judgement of quality is a product of both the individual's assessment of his or her personal experience within a variety of domains and the integration of these observations into an overall judgement...'* Research based on the subjective experience of the patient has attended to this viewpoint and is discussed in more detail in section 3.4.

It could also be argued that in order to understand the process of how QoL judgements are made by patients with cancer or other life-threatening conditions, a model of QoL needs to go beyond disease and treatment related factors (see chapter 2, part I), and incorporate the patient's *representation* of the disease and treatment. These representations may affect the meaning and importance of domains involved in making QoL judgments (Leventhal & Colman, 1997). This may explain why patients experience different levels of QoL, despite having comparable disease and treatment related factors.

3.2.6.2 Empirical evidence of the relationship between components of the SRM and illness outcome [2]

Research studies have made explicit links between illness representations and illness outcomes such as psychological adjustment and QoL. The mediational model proposed by Leventhal et al (1980) shows how the beliefs people hold about their illness influence the coping strategies used, which, it is proposed, affect the outcome (figure 3.1). Due to the mediational effects of coping, there is also evidence of direct effects between illness representations and outcomes.

Many dimensions and subscales of QoL or 'well-being' have been assessed as outcomes in relation to components of the SRM. For example, depression and anxiety have been used as outcome variables, (Rutter et al., 2002; Vaughan, Morrison, & Miller, 2003), in addition to HR-QoL, both disease specific (Han et al., 2005), general HR-QoL (Covic, Seica, Gusbeth-Tatomir, Gavrilovici, & Goldsmith, 2004; Moss-Morris & Chalder, 2003), components of HR-QoL such as physical functioning (Han et al., 2005; Vaughan et al., 2003), as well as general well-being (Helder et al., 2002), overall QoL (Rutter et al., 2002) and adjustment (Groarke et al., 2004; Jopson & Moss-Morris, 2003).

The contribution of illness representations to the well-being of patients with chronic illnesses has also been assessed using a wide-range of illness groups, including most commonly, rheumatoid arthritis (Groarke et al., 2004; Murphy, Dickens, Creed, & Bernstein, 1999; Scharloo et al., 1998; Schiaffino, Shawaryn, & Blum, 1998; Sharpe et al., 2001), chronic fatigue syndrome (Heijmans, 1998; Heijmans et al., 1999; Moss-Morris, Petrie, & Weinman, 1996), diabetes (Eiser, Riazi, Eiser, Hammersley, & Tooke, 2001; Hampson, Glasgow, & Stryker, 2000; Hampson, Glasgow, & Foster, 1995; Skinner & Hampson, 1998), myocardial infarction (Petrie, Weinman, Sharpe, & Buckley, 1996), Addison's disease (Heijmans, 1999; Heijmans et

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[2] A discussion of the literature assessing relationships between illness beliefs and other important outcomes such as adherence to medical regimens or attendance at clinics is beyond the scope of this chapter.

al., 1999), chronic obstructive pulmonary disease (Scharloo, Kaptein, Weinman, Willems, & Rooijmans, 2000), psoriasis (Fortune, Richards, Main, & Griffiths, 2000; Scharloo et al., 1998; Scharloo et al., 2000) and irritable bowel syndrome (Rutter et al., 2002).

The evidence presented above is too lengthy to describe in full, therefore, a few recent key studies specifically reporting the relationships between either illness representations, or coping and QoL (or facets of QoL) will be critiqued.

Studies have demonstrated that illness beliefs may be more strongly related to, and better predictors of outcomes such as QoL than coping strategies (Heijmans, 1998; Moss-Morris et al., 1996; Orbell, Johnston, Rowley, Espley, & Davey, 1998; Scharloo et al., 1998). In particular, having a strong illness identity has been significantly related to poorer outcomes (Heijmans, 1998; Moss-Morris et al., 1996; Scharloo et al., 1998) likewise, strong perceptions of negative consequences have also been reported to be associated with greater impairments on a variety of outcomes (Heijmans, 1998; Jopson et al., 2003; Moss-Morris et al., 1996; Rutter et al., 2002; Scharloo et al., 1998; Vaughan et al., 2003).

The majority of the evidence has been derived from cross-sectional studies, as mentioned previously, however, a recent longitudinal study (Scharloo et al., 2000) investigating the functional status of psoriasis patients one year after recruitment, demonstrated similar results whereby, a strong illness identity was associated with worse outcomes as measured by physical health, social functioning, mental health, health perceptions and depression. Strong perceptions of the negative consequences, were related to negative health perceptions. Illness representations accounted for 3% of the variance in physical functioning at 1 year (baseline physical functioning accounted for 44% of the variance) and passive coping accounted for 2% of the variance. Illness representations (duration and identity) accounted for 12% of the

variance in social functioning. Perceptions of consequence accounted for 4% of the variance in health perceptions.

Another longitudinal study examining whether patient beliefs shortly after myocardial infarction (MI) influenced recovery six months later (HR-QoL), found that initial beliefs were independent predictors of HR-QoL (Horne et al., 2005). Consistent with the findings to date, strong beliefs about the negative consequences of the MI, and that the event was caused by chance, were significantly predictive of poorer physical functioning 6 months later. Similarly, those who perceived the consequences to be high were less likely to recover mental functioning. However, despite their statistical significance, these cognitive variables only accounted for approximately 6-9% of the variance in outcome. Longitudinal studies provide support for causal assumptions made by the authors, however, other explanations for relationships between SRM components cannot be ruled out.

The findings from these individual papers, have been supported by a recent meta-analysis examining the relationship between illness representations and outcomes (Hagger & Orbell, 2003). Six illness outcome categories of: disease state, physical functioning, psychological distress, psychological well-being, role functioning, social functioning and vitality, were identified from the literature. The majority of these could be considered facets of QoL. It was reported that illness representations of consequences, identity and timeline were negatively associated with psychological well-being, role functioning, social functioning and vitality. Consequences, identity and timeline were positively related to psychological distress, suggesting that individuals who perceived their illness to have serious negative consequences, a chronic timeline and a strong identity were more likely to report distress. Likewise, beliefs about cure/control were negatively related to psychological distress. From these results and others, Hagger and Orbell (2003) conclude that their meta-analysis supports the hypothesis that adaptive outcomes, i.e. role, social and physical functioning, psychological well-being and

vitality are associated with lower perceived consequences and a weaker illness identity. Furthermore, these outcomes are also related to beliefs about control. Again, the cross-sectional nature of the majority of the evidence, prohibits any statements regarding causality. The meta-analysis also served to provide support for the consistency of the illness representation dimensions and the strong pattern of relationships between SRM components, however, the possibility of the presence of moderating variables has lead to a certain amount of caution when discussing direct relationships between beliefs and outcomes.

A potential limitation of the research using the SRM, particularly when testing for separate effects, is that many representations demonstrate multi-collinearity, making relationships between outcomes and beliefs difficult to interpret. For example, the association between a chronic timeline and illness identity is accounted for by negative consequences. Another consideration when measuring and interpreting relationships, is that the SRM has been proposed as a feedback model and as such perceptions of outcome could influence the re-evaluation of coping strategies, which may in turn, affect beliefs. This constant re-appraisal makes evaluation of the model difficult and therefore, any findings derived from the model (particularly based on cross-sectional data) may not be static. In addition, lots of different measures of adaptive outcome have been used, with similar patterns between variables emerging, therefore it could be suggested that any relationships found may be measurement artefacts and not indicative of true relationships.

It has also been suggested that cognitive representations should be conceptualised as clusters (or groups) of beliefs rather than interpreted as single cognitions (Heijmans, 1998), however, most of the research presented in this chapter has relied on examining relationships between individual cognitions and outcomes. Similarly, if the intention of the study is to use the results for the basis of an intervention, it must be acknowledged that only fairly small percentages of variance in outcomes are typically accounted for by illness beliefs.

Although this chapter was not intended to provide a systematic review of research using the SRM as a framework, it is clear from the variety of studies presented that there is a distinct lack of published research on the beliefs of general cancer patients in relation to perceptions of outcome. Two papers examining beliefs based on the illness perceptions framework have studied understanding of cancer risk in healthy individuals undergoing testing for a genetic mutation (BRCA 1/2) associated with cancer risk (Kelly et al., 2005) and the validity of healthy women's perceptions of breast cancer patients receiving treatment (Buick & Petrie, 2002). Both of these studies included healthy individuals as the target population and did not assess perceptions in relation to outcomes such as well-being or QoL.

To date, there have been no studies published which have explicitly assessed the illness beliefs of patients with HNC, based on the SRM, and their relationship with outcomes such as QoL or depression. However, Kreitler et al., (1996) investigated the hypothesis that HNC patients' beliefs affect psychological adjustment using the framework of cognitive orientation (CO) theory. CO theory is a general cognitive-motivational theory describing how cognitive contents and processes guide behaviour, including external and internal responses to physical disease and health (Kreitler & Kreitler, 1991; Kreitler, Chaitchik, Kreitler, Rapoport, & Algor, 1996). Based on this theory, four main types of beliefs were identified (beliefs about goals, norms, self and general) that accounted for 40% of the variance in adjustment (as measured by the Patient Adjustment Questionnaire (Rapoport et al., 1993)). Previous studies have shown that scores on these four belief types are successful in predicting behaviours such as overeating (Kreitler & Chemerinski, 1988), smoking behaviours (Kreitler, Shahar, & Kreitler, 1976; Tipton & Riebsame, 1987), and undergoing examinations for the early detection of breast cancer (Kreitler, Chaitchik, & Kreitler, 1994). These studies provide some evidence that behaviour is determined by the endorsement of enough relevant beliefs. Similar to the SRM, CO theory assumes that behaviour is *'the product of interactions among cognitive contents rather than of rational*

decisions' (Kreitler et al, 1996). However, the types of beliefs described in this work focus on beliefs about the self, and the self in relation to the world, whereas beliefs based on the illness perceptions framework focus on the beliefs the individual holds about the illness and the effects of the illness to themselves. Both of these frameworks imply that adjustment to a health threat can result from the modification of relevant beliefs.

3.3 PATIENT EXPECTATIONS AND QOL

Campbell and colleagues have argued that QoL refers to the perceived discrepancy between ideal and real states, and therefore, QoL is higher if this discrepancy is small, and lower if the discrepancy is larger (Campbell, Converse, & Rogers, 1976). Therefore, interventions could be aimed at reducing the mismatch between ideals and experience. One target could be aimed at the expectations people have regarding their QoL after being treated for a disease or illness.

The measurement and definition of expectations is diverse throughout the literature, with many studies not being theoretically based. This has not aided the interpretation of results. For example, Williams and colleagues define expectations in terms of needs, requests or desires (Williams, Weinman, & Dale, 1995), whereas Buetow defines expectations as distinct from wants (Buetow, 1995). However, Like and Zyzanski distinguish between patient expectations and requests by arguing that the former relates to anticipation and the latter refers to hopes (Like & Zyzanski, 1987). This provides a more apposite definition and is expanded upon in chapter 4. Therefore, expectations could be considered as types of cognitive representation, i.e. beliefs about what will happen in the future. With this definition in mind, expectations may play an important role as process variables in outcome judgements.

Calman's contention that QoL assesses the 'difference, or the gap, at a particular period of time between the hopes and expectations of the individual and that individual's present experience' (Calman, 1984a; Calman, 1984b), indicates that QoL will be deemed 'good' when expectations

are fulfilled by experience. Furthermore it may be possible to enhance QoL by narrowing the gap between an individual's expectations and their experience. This could feasibly be done by modifying expectations through accurate information concerning the benefits, risks, alternatives, and outcomes of treatment. Calman (1984b) suggests that reducing expectations does not deny hope, but helps patients develop realistic goals.

Based on Calman's definition of QoL, Wan and colleagues conducted a cross-sectional study of the effects of expectations on HR-QoL (Wan, Counte, & Cella, 1997). A convenience sample of 466 cancer patients (including 32 HNC) completed the FACT-G (Cella et al., 1993) and also rated each of the items on the FACT-G according to whether their expectations had been met (worse, better or as expected). Expectations (amongst other variables) were found to exert a significant effect on HR-QoL, whereby patients reporting better than expected HR-QoL were more likely to have higher overall HR-QoL scores. An important limitation of these findings is that if a significant gap existed between expectations and experience, patients may have changed their ratings to ease any discomfort they might have felt (Festinger, 1957).

The SRM has been applied to one study of the pre-operative expectations of patients undergoing oral surgery to extract third molars, in order to test the predictive power of expectations on recovery (McCarthy, Lyons, Weinman, Talbot, & Purnell, 2003). Expectations were derived from rewording the IPQ in order to elicit patient beliefs about what they thought would happen after surgery in terms of the five key illness representations (identity, timeline, consequences, cure/control and cause). It was found that pre-operative expectations predicted symptom severity, psychological distress, speed of return to work and healing rates at follow-up, better than medical factors. More specifically, pre-operative expectations of symptom severity (illness identity) were a primary predictor of symptom severity after surgery, controlling for length of stay, number of teeth removed, difficulty of surgery or anxiety.

Pre-treatment expectations have been found to be predictive of nausea after chemotherapy in patients with cancer (Hickok, Roscoe, & Morrow, 2001). Similarly, another study reported that pre-treatment expectations were related to post-treatment nausea whilst controlling for levels of emotional distress. It was also indicated that the influence of expectations on nausea changed with patients experience of chemotherapy (Montgomery & Bovbjerg, 2000). In contrast, a study by Andrykowski and Gregg found nausea post-chemotherapy was not related to pre-treatment expectations but levels of state anxiety (Andrykowski & Gregg, 1992).

Other evidence from the literature has shown that pre-treatment expectations influence other outcomes such as; QoL (Koller et al., 2000), HR-QoL (Staniszewska, 1999; Wan et al., 1997) and functioning (Iversen, Daltroy, Fossel, & Katz, 1998; Mahomed et al., 2002) in a wide range of illness groups such as cancer, cardiac and arthritis patients.

Methods of assessing expectations have varied across studies and many of the studies have been cross-sectional which means questions regarding the predictive role of expectations remain unanswered. In addition, it has long been suggested that expectations and optimism are closely linked and many studies assessing the effects of expectations on outcome have not controlled for levels of optimism. Accumulating evidence has demonstrated that dispositional optimism is beneficial for many psychological and physical outcomes. A study by Scheier and colleagues for example, reported that optimistic men evidenced a more rapid physical recovery after coronary artery bypass surgery and reported a higher quality of life 6 months later than the more pessimistic males in the sample (Scheier et al., 1989). Differences in outcome have been suggested to derive from differences in the way optimists and pessimists cope with the challenges of life. As Scheier and colleagues (1994) have noted, 'optimists are people who tend to hold positive expectancies of their future; pessimists are people who tend to hold more negative expectations for the future' (Scheier, Carver, & Bridges, 1994). Optimists have been found to differ from pessimists in the way in which they cope with serious disease (Friedman et

al., 1992) and with concerns about serious health threats (Carver et al., 1993; Taylor et al., 1992). Much of the research suggests that optimists tend to use more problem-focused coping strategies than pessimists, and when this is not possible, optimists turn to more adaptive emotion focused strategies such as acceptance, use of humour and positive reframing of the situation (Scheier et al., 1994). These findings are consistent with their model of behavioural self-regulation (Carver & Scheier, 1981; Scheier & Carver, 1988) whereby individuals are seen as remaining engaged in efforts to overcome adversity to reach goals as long as their expectancies of success are high. These differences in expectancies are also paralleled by variations in affect. If goal attainment is slower than anticipated, people will experience negative affect, whereas if it is faster than positive affect will result. This can be equally applied to individual differences (e.g. optimism) as a process underlying behaviour. Little is known as to whether expectations are purely the product of dispositional optimism or a result of situational factors such as the information the patient has been given about likely outcomes.

Despite these limitations, evidence suggests that positive expectations are associated with better health outcomes in patients with a variety of clinical conditions. A greater understanding of the role of expectations on outcomes such as QoL, anxiety and depression, independent of optimism, may improve the process of care and outcomes after treatment. In addition, clarifying the influence of other factors, such as the role of information, on the formation of expectations, may assist with the targeting of appropriate interventions to enhance outcomes.

3.4 ADAPTATION TO CHANGING HEALTH – THE PROBLEM OF 'RESPONSE-SHIFT' IN QOL DATA

The previous sections have highlighted how the perception of QoL could be considered a dynamic construct due to judgements varying over time and with experience of illness and treatment. Secondly, outcomes such as QoL, health status and depression, have been shown to be influenced by psychological factors such as perceptions about the illness, coping strategies

and expectations. The inclusion of QoL measures in health related research is well accepted and is valuable in the context of understanding how ill people adapt to their changing health state and any functional limitations. However, it has long been recognised that QoL research sometimes yields findings that are paradoxical; in terms of the QoL of ill samples as compared to healthy samples, and also in terms of improvements in QoL despite deteriorating physical condition. It is likely that individuals, when faced with a serious health threat such as cancer, redefine their internal standards of what constitutes health and reflect upon the meaning of their lives, this may lead to a shifting of goals. Similar to the dynamic process of constant reappraisal of beliefs and coping strategies outlined in the SRM, the construct of 'response-shift' may be able to account for any disparities between clinical indicators of health and patient's own perceptions of QoL.

3.4.1 The construct of response-shift

Response-shift is of particular importance when individuals undergo a change in health state as this is when changes in internal standards, values or conceptualisation of QoL may occur in order to accommodate the illness or condition. The working definition of response-shift refers to a change in the meaning of one's self-evaluation of a target construct, such as QoL, as a result of three interrelated constructs (Schwartz, Sprangers, Carey, & Reed, 2004). 1) A change in the individual's internal standards (process of recalibration); 2) a change in values or priorities (reprioritisation); or 3) a change in the definition of the target construct (reconceptualisation) (Schwartz et al., 1999; Sprangers & Schwartz, 1999). Similarly, attitudes towards a construct do not remain stable over time and are modified by psychological factors such as adaptation, coping, expectancy, optimism and self-concept, (Allison, Locker, & Feine, 1997), judgements concerning QoL are amenable to fluctuation. As highlighted above, this is not necessarily as a result of changes to physical parameters but may be due to changes in the person's point of reference.

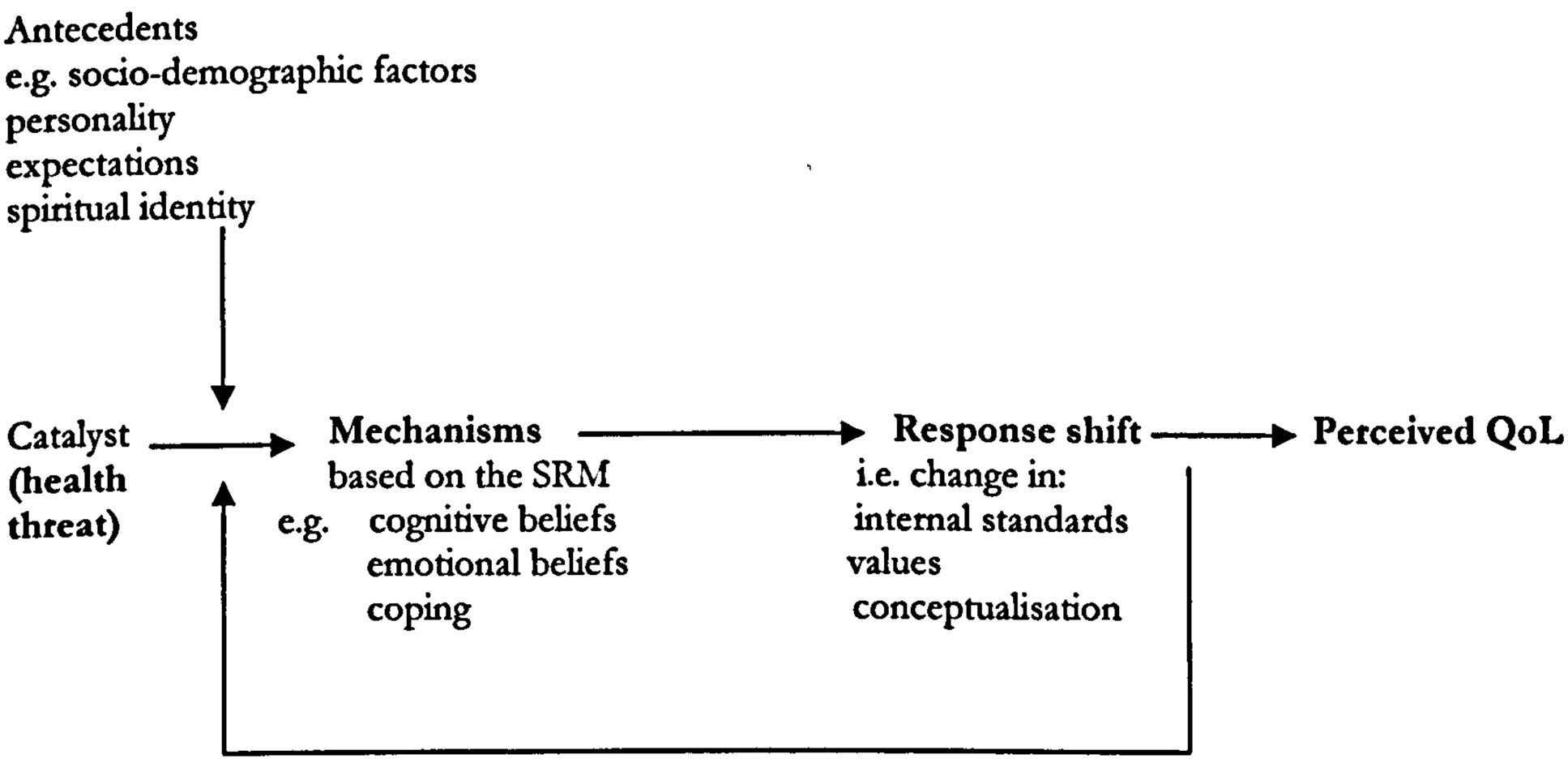
The literature provides examples of counter-intuitive findings which could be interpreted as evidence of response-shift. For example, Cassileth and colleagues found the psychological well-being of skin cancer patients to be significantly better than that of a sample of patients with other skin disorders and slightly better than that of the general population (Cassileth, Lusk, & Tenaglia, 1984). Similarly, in a study of transplant recipients, haemodialysis patients and others, patients' levels of happiness, satisfaction or life quality often exceeded that of a healthy population (Evans, 1991). Other research has demonstrated that people with severe chronic illness do not report worse levels of QoL than less severely ill or healthy samples (Andrykowski, Brady, & Hunt, 1993; Breetvelt et al., 1991; Groenvold et al., 1999). In addition, studies highlight the discrepancy between clinical measures of health and patients' own evaluations (Daltroy, Larson, Eaton, Phillips, & Liang, 1999; Kagawa-Singer, 1993) and thus demonstrate the problems in the area of QoL research.

Recent research has demonstrated that individuals seek to make sense of traumatic experiences and find benefits from them. A study by Taylor in 1983, found approximately half of women diagnosed with breast cancer reported finding benefit in the form of positive changes in their lives since diagnosis (Taylor, 1983). More recently, research with cancer patients has demonstrated many types of benefit derived from the situation (Antoni et al., 2001; Cordova, Cunningham, Carlson, & Andrykowski, 2001; Sears, Stanton, & Danoff-Burg, 2003) and an association between benefit finding and lower distress and depression at follow-up (Carver & Antoni, 2004). Benefit finding has been likened to a profound shift in priorities which promotes personal growth, arising from the challenge of serious illness (Sears et al., 2003).

Sprangers and Schwartz propose a theoretical model which addresses how response-shift may affect outcomes such as QoL (Sprangers et al., 1999). This model consists of five components: The catalyst refers to the change in health status, the antecedents refer to stable characteristics of the patient i.e. socio-demographic variables, personality traits and expectations. The

mechanisms refer to behavioural, affective and cognitive processes in response to the catalyst. Examples of mechanisms provided by Sprangers & Schwartz (1999) include using coping strategies; making social comparisons; seeking social support; reordering goals; reframing expectations and engaging in spirituality. The model as shown is simplistic, but shares similarities with theories of self-regulation, in that the model is meant to represent a dynamic process of feedback (similar to the SRM) and response shift may be influenced by optimism and affect as suggested by Carver and Scheier's self-regulatory model (Carver et al., 1981; Scheier et al., 1988) .

Figure 3.2 A theoretical model of response shift and QoL based on Sprangers & Schwartz (1999)



The theoretical model has been reproduced in Figure 3.2 and modified to include explanatory variables based on the SRM. It is plausible that the mechanisms for response-shift may be explained by the dynamic interaction between beliefs and coping. For example, QoL judgements may indirectly result from a process of reappraisal of coping based on their beliefs about the illness and treatment. If the individual feels they have successfully coped with the health threat then a positive reinterpretation of the situation may occur. This leads to a response shift due to a change in internal standards (recalibration) or a change in values or

priorities (reprioritisation). This in turn leads to the reconceptualisation of what QoL means to the person.

The meta-analysis by Hagger and Orbell (2003) described previously, demonstrated that illness beliefs such as controllability of the illness influenced coping strategies. It is plausible that these particular beliefs and others such as, identity and consequences, influence and drive the process of response shift through the use of adaptive coping strategies such as cognitive reappraisal.

3.4.2 Measurement issues

Although response-shift has recently been applied in the context of QoL research (Schwartz & Sprangers, 2000), the concept has its foundation in educational training (Howard & Dailey, 1979; Howard, Dailey, & Gulanick, 1979) and organisational research (Golembiewski, Billingsley, & Yeager, 1976) both of which provide differing definitions of the phenomenon. Howard and colleagues defined response shift in terms of changes in internal standards, whereas, Golembiewski and colleagues combined the idea behind reconceptualisation with scale recalibration. The extent that the three components of response shift as defined by Schwartz and Sprangers are interconnected or distinct is unknown and it has been suggested that the interconnection between aspects may be hierarchical in nature. For example, Golembiewski and colleagues assumed that changes in internal standards cannot be assessed if reconceptualisation of the target has occurred. However, Schwartz and Sprangers (2000) have argued for a more dynamic theory, whereby changes in internal standards may affect the conceptualisation of the construct, therefore, the reverse will occur.

Researchers of response-shift are essentially critical of standard methodologies to assess longitudinal outcomes typically involve the traditional 'pre-test, post-test design', which assume conclusions can be made about the relationship of variables over time. This standard

methodology is based on the common assumption that an individual's internal standard of measurement is stable and will not change over time.

Early response shift research utilised Golembiewski et al's (1976) methods of measurement of change that distinguished actual change (α change) from changes in internal standards (β change) and meaning (γ change). Beta change allows for the fact that a persons terms of reference may have changed in the light of their experience for example, the 'worse possible pain' changes when pain does actually get worse. Gamma change involves a redefinition or reconceptualisation of a domain, for example, a major change in the perspective or frame of reference, especially with complex multidimensional constructs such as QoL. Gamma change is the most profound change, which can confuse the evaluation of alpha change. Therefore this has to be controlled for in the covariance analysis typically used to assess this type of response-shift. This methodology does not allow for the evaluation of the reprioritisation component of response shift.

Howard et al., (1979) proposed an extension of the pre-test, post-test design by using a 'then-test' (a retrospective pre-test). At post-test, two measures are completed - how people presently perceive themselves, and how people perceive themselves to have been prior to the intervention (or disease). This is to provide a renewed judgement of their pre-treatment functioning. It is hypothesised that most work using a traditional pre-test, post-test design are biased by 'response-shifts'. However, one major critique of this method is that it relies on an accurate memory regarding previous situations. Whether this is valid in the light of any recalibration that may subsequently have occurred is open to debate.

There are many other methods for accounting for response-shift biases, including 'informed questionnaire' approaches, whereby patients are given access to their pre-test responses and asked to rate how they are in relation to scores provided previously. This is to avoid the

problem of recall biases, however, this method may actually serve to prompt individuals to act in a consistent way and not as they really feel.

One of the major problems with assessment is that response-shift is an abstract concept that is difficult to measure directly. One solution is to use specially constructed questionnaires that allow for the assessment of reprioritisation. Instruments to assess QoL (or individualised QoL) overcome problems with the traditional pre-and post-test by examining how domains change over time and with experience of a changing health state. Two such measurement instruments are the Schedule for the Evaluation of Individualised Quality of Life (SEIQoL) (O'Boyle et al., 1994) and the Patient Generated Index (PGI) (Ruta, Garratt, Leng, Russell, & MacDonald, 1994) both of which assess changes in values and priorities (reprioritisation).

A full discussion of the methods for assessing response shift are beyond the scope of this chapter but can be found in the following references (Patel, Veenstra, & Patrick, 2003; Schwartz et al., 2000). A critique of the PGI as a suitable methodology for the assessment of individualised QoL in HNC patients can be found in chapter 10.

3.4.2.1 Clinical implications

Response shifts are more likely to occur in some domains of HR-QoL than others. As biological and physiological parameters are not in general assessed by self-report, these are not subject to response shifts, likewise some measure of functioning are more concrete than others (Wilson, 1999). For example, functioning such as activities of daily living (e.g. walking without assistance) are unlikely to undergo response shift as they are not tasks at risk of scale recalibration, however the *priority* a person places on the functional limitation may change (reprioritisation). Similarly, perceptions of symptoms can vary in meaning, intensity and concern which means they are feasibly subject to recalibration or reconceptualisation (comparable to changes in illness identity as assessed by the illness perceptions framework).

Response shift is a part of routine clinical practice and as such poses particular challenges for clinicians.

In addition, the absence of response-shift may account for maladaptive outcomes after a health threat, seen for example, in situations where the health status or functioning does not actually deteriorate but perceptions of QoL and other outcomes such as depression and anxiety do decline. In summary, explicitly considering response shift may lead to a better understanding of the process of adaptation and may increase the benefit of assessing QoL as an outcome.

3.5 IMPLICATIONS OF REVIEWS TO THESIS

The reviews presented in chapters 2 and 3 have highlighted the paucity of theory driven research examining the predictive factors of patient outcomes such as QoL in patients with HNC.

Of particular interest are the informational requirements of patients with HNC. It has not been established in the literature as to whether the mismatch between patients' informational requirements and the information received plays a role in outcomes such as QoL, and anxiety and depression.

As discussed in this chapter, the complex relationships between processes detailed in the SRM and health outcome such as QoL are difficult to disentangle. This is due to much of the evidence being based on cross-sectional designed studies. Therefore, in the thesis, a longitudinal study design is adopted to allow for the assessment of components of the SRM and cognitive and emotional outcomes to be assessed at multiple time-points, which may assist in unravelling some of these complex relationships. It also allows for more proximal predictive relationships between illness representations and outcomes to be defined.

A third main implication to arise from a review of the literature, is the use of an individualised measure of QoL in order to assess aspects of response shift and also to investigate whether this would provide a more appropriate measure of QoL than standardised measures traditionally used with HNC patients. Suggestions made by Leventhal and Colman (1997), indicate that individualised measures may provide better outcomes for predictive studies based on SRM components.

In conclusion, the study of QoL using a theoretically driven approach, may provide a deeper insight into the nature of QoL and the psychological processes that determine it. Furthermore, it is anticipated that factors found to be predictive of outcomes may be subject to modification and used to inform future intervention studies to enhance patient outcomes after treatment for HNC.

3.6 MAIN AIMS AND OBJECTIVES OF THESIS

The main aim of the thesis was to investigate the role of psychological factors in predicting quality of life in patients diagnosed and treated for head and neck cancer. A self-regulatory framework was used as reference for guiding the selection of psychological factors related to adaptation and outcome.

There were seven key objectives for the research:

1) To explore the informational needs of HNC patients and the relationship between satisfaction with information and key outcomes *(Chapters 4, 5: Part 2 & 6).*

2) To assess the impact of HNC on QoL using two distinct measures: a) standardised measures of HR-QoL (generic and cancer specific) and b) an individualised (patient centred) measure of QoL *(Chapters 7 &8).*

3) To assess the degree of concordance between the two main types of outcome measures *(Chapter 7).*

4) To apply Leventhal's Self-regulatory model (SRM) to guide understanding of the processes by which HNC patients understand and react to their illness and to assess how these change over time *(Chapters 7 & 8).*

5) To investigate how particular variables specified within the SRM (e.g. illness representations and coping responses) are related to outcomes *(Chapters 7 & 8).*

6) To explore whether additional factors such as the extent to which patients are satisfied with information, can partially explain outcomes *(Chapters 6 & 8).*

7) To explore whether psychological factors (illness and treatment beliefs) or clinical and treatment related variables are better predictors of adaptation over time *(Chapters 8 & 9).*

More specific aims and hypotheses relating to each study are presented at the beginning of each empirical chapter.

CHAPTER 4

AN IN-DEPTH EXAMINATION OF THE EXPECTATIONS AND INFORMATIONAL NEEDS OF HNC PATIENTS: A QUALITATIVE PILOT STUDY

This chapter has been published: Llewellyn CD, McGurk M, Weinman J. (2005) Striking the right balance: a qualitative pilot study examining the role of information on the development of expectations in patients with head and neck cancer. *Psychology, Health & Medicine*, **10**:2;180-193.

4.1 INTRODUCTION

The diagnosis of cancer itself is frightening for patients and their families. Cancer of the H&N not only poses a threat to life but, as highlighted in chapter 2, the consequences of the disease and treatment can be far-reaching and especially traumatic if unanticipated. These unexpected consequences may, in turn, lead to long-term difficulties with adjustment and therefore affect patient outcome in terms of QoL and depression. Evidence from the literature (see chapter 3) has shown that pre-treatment expectations influence recovery from surgery, (McCarthy et al., 2003) and HR-QoL after radiotherapy (Koller et al., 2000) and HR-QoL during in-patient stays (Staniszewska, 1999) in a wide range of illness groups.

Although unforeseen complications can arise, some of the uncertainty and trauma could be lessened with accurate and timely information at a level that patients can understand. For example, Leydon et al., (Leydon et al., 2000) demonstrated that not all patients want extensive information about their condition and treatment at *all* stages of their illness. However, patients undergoing surgery often experience considerable anxiety as a result of receiving too little information or information that they cannot understand (Krupat, Fancey, & Cleary, 2000). Studies have shown that the majority of written pre-operative instructions are not understood by patients (Livingston, 1989) and in another study, that only 60% of cancer patients could correctly describe their treatment (Cassileth, Zupkis, Sutton-Smith, & March, 1980).

In addition to the timing and format of the information supplied, another key issue is the mechanism by which information benefits the patient. Janis (Janis, 1958) argued that pre-operative information allows patients to engage in 'work of worrying'. He proposed that information is useful because it allows patients to anticipate and rehearse the stressful events they are about to encounter and therefore cope more successfully with them. However, it has also been recognised that the benefits of information may vary considerably according to the timing of the information (Pinder, 1990) and the personality and demographics of the patient (Mahler & Kulik, 1991; Miller & Mangan, 1983).

Despite the growing volume of research into the informational needs of patients with cancer in general, little is known specifically about the informational requirements of patients with highly traumatic diseases such as HNC. It is also not known whether the mismatch between these informational requirements and the information received plays a role in the development of expectations.

4.2 AIMS

This qualitative study sought to examine in depth:

1) The types of expectations patients had prior to treatment and the extent to which patients considered that these expectations had been met post treatment.

2) The role of information on the development of expectations.

4.3 METHOD

4.3.1 Recruitment of participants

Patients were recruited from head and neck cancer clinics run at two London Hospital NHS Trusts (King's College Hospital NHS Trust and Guy's & St Thomas' Hospitals NHS Trust) and were based on a convenience sample. This was to minimise any bias that may have been created by pre-selecting patients into the study. Patients may have been more likely to talk

about their experiences in the context of a clinical review visit than returning on a separate occasion. Recruitment criteria were any post-treatment patient up to eighteen months post-diagnosis and currently free of disease. The cut-off point of eighteen months post-diagnosis was for several reasons. Most importantly to ensure that experiences were relatively recent to avoid problems with recall, secondly, to explore a spectrum of opinions at different stages of treatment and recovery and, thirdly, for more practical reasons of increasing the sample eligible for recruitment. Patients were recruited during the period from 10th January 2003 to 5th March 2003. Ethical approval for this study was granted by the local research ethics committee and consent was obtained from all participants.

4.3.2 Data collection

The interviews were conducted in various quiet rooms in the clinics. The interviews were semi-structured in design although many interviews were based quite loosely around the topics determined by the interview schedule (Appendix IV) and the schedule was used more as an aide memoire according to the patient and the type of responses given. The interviews were iterative from the beginning, meaning that the first interview schedule was transformed over the first few interviews according to the usefulness and responsiveness to certain questions. Interviews typically began with a short discussion about why they were in the clinic that day and how long it had been since they had first been diagnosed, in order to establish rapport. A broad opening question such as; 'could you describe for me some of the experiences you have gone through since your diagnosis?' then followed and participants were prompted to think back over their experiences and expectations if required. Questions were presented in as neutral way as possible to minimise potential bias. The interviewer encouraged the participant to elaborate on stories and situations to illustrate important points.

All interviews were tape-recorded and lasted between approximately fifteen to fifty-five minutes, the average being about thirty minutes in duration. Transcripts were produced shortly

after each interview. Demographic and medical data were collected from hospital medical records.

4.3.3 Data Analysis

Data were analysed using a Framework Analysis Approach (Ritchie & Spencer, 1994). This is a matrix-based approach to qualitative data analysis, which is based on transcripts produced verbatim from the taped interviews. This technique involves identifying recurring and important themes based on a combination of a-priori issues, emergent themes and recurring attitudes or experiences. Major themes in the data arising in these transcripts (determined by an initial read through of all the transcripts and then an in-depth analysis of the first seven transcripts) were then used as headings/themes under which the systematic charting of the content of all the transcripts was carried out. This ensured that the themes could be refined. Any new themes that subsequently arose were added to the framework. This method ensured that the diversity of the participants' experiences was encapsulated. Analysis was carried out after all the participants had been interviewed and this was to minimise the potential bias of the results of one interview influencing the next based on any framework that subsequently emerged.

4.3.4 Reliability of the data

In order to comment on the reliability of the data, a second rater (CK) was given the framework of emergent themes/headings and the verbatim transcripts and asked to appraise them according to their content. The few discrepancies that arose were discussed until inter-rater satisfaction was achieved.

Table 4.1: Characteristics of participants

Pt. no.	Current age (yrs)	Sex	Approx. time since diagnosis in months	Approx. time since end of treatment in months	Site of cancer	TNM‡ stage	Type of operation	Total treatment modality*
1	47	F	12	9	Maxillary/gum	T stage unknown N0M0	Hemi-maxillectomy	S, RT, ND
2	42	F	15½	15	Maxillary	T2N0M0	Hemi-manibulectomy, maxillectomy	S, ND
3	56	M	18	15	Mandible/ floor of mouth	T4N2M0	Mandibulectomy + free-flap	S, ND
4	51	M	5	2	Tongue	T3N0M0	Glossectomy	S, RT, ND
5	49	M	7½	2	Maxillary	T4N0M0	Maxillectomy + free-flap	S, RT, ND
6	55	M	1½	1 (pre-RT)	Mandible	T4N1M0	Mandibulectomy + free-flap	S, ND pre-RT
7	61	F	12	11	Maxillary	T4N0M0	Hemi-maxillectomy + free-flap	S
8	75	M	10	6	Tongue/ floor of mouth	T2N1M0	Glossectomy +free-flap	S, IRT, ND
9	70	F	12½	11	Palate	Low grade Adenocarcinoma	Local excision	S
10	48	F	4½	1½	Tonsil	T1N0M0	-	RT, CT
11†	63	F	Not known	9	Mandible	T4N0M0	Hemi-mandibulectomy + free-flap	S, RT, ND

Pt. no.	Current age (yrs)	Sex	Approx. time since diagnosis in months	Approx. time since end of treatment in months	Site of cancer	TNM‡ stage	Type of operation	Treatment modality*
12	59	F	12½	12	Tongue	T1N0M0	Partial glossectomy	S, ND
13	47	F	3½	3	Floor of mouth	T2N0M0	Partial glossectomy +free-flap	S, ND
14	38	F	9	7	Floor of mouth	T3N1M0	Partial glossectomy +free-flap	S, IRT
15†	43	F	15	10	Cheek/ floor of mouth	T4N0M0	Mandibulectomy +free-flap	S, RT, ND

† = 2 patients contracted post-surgical Methicillin-Resistant Staphylococcus Aureus (MRSA)
‡ = TNM staging of tumour (American Joint Committee on Cancer, 1988)
* S=Surgery; RT=radiotherapy; IRT=Irradium wire implant therapy; CT=chemotherapy; ND=Neck dissection

4.4 RESULTS

4.4.1 Profile of participants

Participants were fifteen patients treated for head and neck cancer and under the care of two maxillo-facial/oral surgery consultants, attending clinics at two south London hospitals. One male patient refused to take part and one taped interview (also a male patient) had to be discarded due to extraneous background noise. This gave a response rate of 88%.

Table 4.1 provides a breakdown of the demographic and treatment profiles of the participants. Ten participants (67%) were female. Ages ranged from 38 to 75 (mean=54; median=51; SD=10.5). All patients except two (one Asian and one Iranian) classified themselves as white UK ethnic origin. The time since diagnosis ranged from 1½ to 18 months (median=9; mean=9.7; SD=4.8). All tumours except one (adenocarcinoma) were squamous cell carcinomas (SCC). Three patients had carcinoma of the tongue, three of the mandible, four of the maxillary region, three floor of mouth and one each of the tonsil and palate. All patients except one had surgical treatment and the majority also had radiation therapy. All patients were free of disease at the time of interview.

Two main themes of 'patient expectations' and 'the role of information' were explored, which resulted in a number of sub-themes (see Table 4.2).

Table 4.2: Structure of main themes, sub-themes and examples of issues to emerge from interviews

Main Theme	Sub-theme	Example of issues to emerge
1. Patient Expectations:	Global	Unexpected enormity of treatment / recovery
		Expectations being surpassed by reality
	Specific	Side-effects of treatment
		Aesthetical outcome
		Recovery as a process
2. Information influencing expectations through:	Too much information	Limits to how much info can be 'taken in'
		Repercussions on ability to cope
	Too little information	'Missing' information
		Lack of clarity
	Timing of information	Knowledge gap
		Uncertainty

4.4.2 Part 1: Patient Expectations

Respondents described expectations reflecting two central themes: *'Global'* expectations regarding the whole cancer 'experience' and more '*specific*' expectations, centred around side-effects, aesthetic aspects and the recovery process. This was interwoven with explanations as to the origins of their expectations and their views on their satisfaction with the information they had received about their treatment and recovery.

Figures after quotes refer to the interview no., sex and age of the participant.

4.4.2.1 Global Expectations

A large proportion of respondents described the whole experience as being worse than they had imagined. A few patients expressed a sense of unexpected 'enormity' about the surgical treatment and the subsequent physical recovery process, particularly those who had also received radiotherapy, as emphasised by:

'I didn't realise how big it was all going to be...Even had I been told, I don't think I would have expected what happened'. [2,F,42]

'.....he (the surgeon) tells me it's not dangerous – it's not a big operation. But when I come here I was surprised – it was a big operation'. [4,M,51]

'I'll be quite honest, I didn't realise the operation at the time would pull me down as regards health so much. I think because I lost so much weight, I felt so weak. It affected me more than I thought it was going to at the time.' [9,F,70]

Similarly, patients reported feeling surprise (post-treatment) at the extent of the operation due to the relatively small part of the lesion visible to the patient. The fact the tumour was extensive but not visible had obviously not been explained to the patient:

'I wasn't expecting such a large area (affected) from what seemed such a small, well, not a small operation, but such a large affected area from a small area that was involved in the surgery'. [12,F,59]

A few respondents reported that the whole cancer experience had been better than they had been expecting. One woman described how she felt physically better now than she had thought she would:

'Well, I did think that I may feel worse actually. Everybody says you'll feel tired and you won't be able to do this or won't be able to do that but I'm doing everything so...' [10,F,48]

Similarly, another woman reflected on her ability to cope, despite not having any concrete expectations:

'I think I've actually done better than what I thought I might. Because you don't know. You just don't really know, well, I didn't know what to expect. Perhaps I didn't ask enough questions but then I didn't want to know...I think I've coped a lot better than I thought I would'. [1,F,47]

4.4.2.2 Specific Expectations

4.4.2.2.1 Side-effects

Expectations regarding specific outcomes of treatment and recovery reflected both positive and negative aspects. Respondents were able to describe their experiences of specific side effects that had exceeded their expectations, for example,

'There was a lot less pain than I expected. I was able to eat quite quickly and I was able to talk better than I thought I would'. [12,F,59]

'I was also told that they didn't think that I would speak for six months, but I did. As soon as they took me off tracheostomy, they could understand me basically, so that was a bonus'. [14,F,38]

Conversely, a few respondents recalled their surprise at experiencing arm and shoulder mobility problems (due to the neck dissection):

> *'I had mobility problems for quite some time which I hadn't expected. I couldn't raise my left arm very much...I wasn't expecting as much numbness...' [12,F,59]*

One patient, at a relatively early stage since diagnosis (5 months) described his current situation after undergoing radiotherapy:

> *'It's all a lot worse than I thought it would be. I can't eat because I have no saliva both sides, it's very dry'. [4,M,51]*

4.4.2.2.2 Aesthetics

Aside from functional aspects, disfigurement immediately after the operation was a particularly emotive issue due to the uncertainty surrounding the extent of surgery. Many respondents chose not to look at themselves immediately afterwards due to the large amount of swelling, however, one woman's expectations were surpassed when she finally looked at herself a week later:

> *'I actually looked a hell of a lot better than I thought I would...'cos I thought I might lose a cheek or outer skin whereas all mine is internal'. [1,F,47]*

Respondents tentatively expressed expectations and hopes regarding future aesthetic improvement, either for further cosmetic procedures or healing with time.

4.4.2.2.3 The recovery process

Expectations regarding the recovery process seemed realistic in some people who recognised that recovery would take place over an extended period of time and would be challenging. For some people, pre-treatment expectations had been less realistic in hindsight, with expectations that after a couple of months they would be feeling the same or better than they had at

diagnosis. For example, expectations regarding current health status, were mentioned by a couple of respondents. One woman struggled to conceal her disappointment at not recovering as quickly as she was expecting and attempted to put it in perspective by suggesting her expectations may have been unrealistically optimistic:

> *'I had expected it to be a little better. Maybe I was just being overly optimistic, you know (pause) but I don't expect (pause) I mean, the important thing is that the cancer is gone but I had some major setbacks on the ward'. [15,F,43]*

Additionally, one woman described how she was expecting physical changes but was uncertain how they would manifest. She also recalled not expecting any psychological problems. However, she was currently experiencing panic attacks related to her loss of confidence and altered appearance:

> *'Well, I did expect that there might be some big changes, perhaps physically. I didn't expect any psychological problems but I did expect to be physically different and I wasn't sure what that would mean'. [12,F,59].*

Expectations regarding recovery were also revealed through expectations of returning to work. Expectations appeared to be related to prior advice from the consultant and comparison with other patients who had undergone similar procedures. These proved to be exceeded in some. For example;

> *'Mr X said it would be minimum 6-7 months up to a year, 2 years depending on individuals. I was actually back at work in November, the November after the April (7 months)'. [1,F,47]*

Prior expectations had not been met in others:

> *'It had been my expectation to go back to work at the end of this month, having finished the radiotherapy at the end of October. I thought 4-5 weeks recovery, back to work. But no'. [5,M,49]*

4.4.2.2.4 Early optimism versus later realism

Despite respondents later being able to concentrate on specific expectations they recalled having, many patients denied having any pre-treatment expectations or thoughts about what was going to happen to them in the future. The reasons given for this ranged from being too busy at the time to having difficulty trading off the need to be realistic whilst trying to be optimistic. This may have been due to the coping strategy employed at that particular time. For example:

> 'I didn't really have any [expectations]. I was too busy and I was just trying to cope with things'.[11,F,63] *and* 'My expectations (pause). I can't really give you a straightforward answer because again it's this, you know, being realistic and being optimistic (laughs)..so I don't have a clear cut…'[13,F,47]

Moreover, another respondent talked about the difference between her expectations for the future and her hopes:

> 'I hoped to feel like I had before. Those were my hopes but not necessarily my expectations'. [12,F,59]

Patients' expectations were reported to change over time. Many post-treatment patients confided how shocked they were at the extent to which life in general had actually changed afterwards, despite expecting some alteration. A few respondents mentioned that their expectations changed throughout the recovery and the post-treatment period, lowering with experience of complications or problems. One respondent reported that she had learnt to be more patient regarding the speed of recovery after her expectations had not been met. This appeared to suggest that many people were optimistic in the early stages of the recovery process, but, with time and experience, people later developed more realistic expectations, suggestive of adaptive processes taking place.

4.4.3 Part 2: The role of information on the development of expectations

Many respondents presented a conflicting picture of needs and requirements, between not wanting too much information on the possible complications and side-effects associated with treatment but feeling in hindsight that they were 'missing' information regarding specific events. Explanations for this variation were forwarded by respondents, mainly relating to pre-treatment fear and perceived ability to cope with too much knowledge. The mismatch between informational requirements and satisfaction with the amount of information actually received, appeared to affect their ability to cope, feelings of 'preparation' in some people, amount of anxiety experienced before and after treatment and uncertainty and conflict in others.

4.4.3.1 Too much information

Many respondents reflected that they had not wanted 'too much' information pre-operatively. This appeared to be related to two factors. Firstly, fear over having too much knowledge about the potential negative effects of treatment, and secondly, a perceived lack of ability to cope. These factors were illustrated by statements such as:

> *'I only needed to know what was needed to be known. Because if I'd had too much information you would have found me in the corner with a vodka bottle'. [1,F,47]*

and also;

> *'there's a limit to how much one can take in actually on something like this and how much you can actually cope with. Sometimes if you knew, like, any challenging thing you have to go through - if you knew all the horrible things that were going to happen you'd be like, 'no way! Thanks a lot'. [13,F,47]*

When asked whether respondents were satisfied with the information they had received, the majority expressed satisfaction. Satisfaction with information also corresponded to feelings of preparation before and amount of worry after surgery for some of the respondents. One respondent, in hindsight, felt that preparation was tied into knowing the extent of the 'long-

haul' of recovery. However, it was felt by some people that there was a limit to how prepared they could feel before such a major operation. One respondent asserted that being prepared and ability to cope were linked to personality not the information supplied, in addition, a further respondent did not consider preparation to be linked to knowledge as she had not felt at all prepared. However, this particular respondent had been very fearful of the whole procedure and admitted she hadn't read or taken in any of the information due to her strong apprehension.

4.4.3.2 Too little information

Although the general level of satisfaction with information was reported to be high, a few respondents reflected that there had been a distinct lack of information on the long-term impact on life and information on financial benefits available. For many respondents who reported 'missing' information pre-treatment or misunderstandings between the explanation provided and their experience, psychological consequences (such as anxiety and depression) were revealed post-treatment. A few respondents reported unexpected long-term side effects which they related to 'missing information'. For example:

> *'One thing I was very shocked by was that I couldn't speak after the operation...It took a couple of weeks until I was sure I was going to be able to talk. The other thing I was very numb....No, I hadn't known about that. So it was quite missing information. I was quite shocked by that because I really had been expecting that the numbness would be temporary'. [13,F,47]*

Expectations were clearly related to the information given by the treating staff and the risks associated with the particular treatment recommended. Many respondents reported some aspect of treatment or recovery that they were not told of (or could not recall being told). There was a common lack of clarity regarding the effects of radiotherapy, from hardening of the scar tissue from surgery or developing bald patches on the head, to major complications of

failure of facial skin grafts. Many respondents reported a lack of understanding regarding how the effects of radiotherapy would make them feel 'setback' after recovery from surgery.

The variance between what to expect derived from detailed information and the actual experience was dramatically highlighted by one respondent:

> *Nearly all that's happened, the doctors told me beforehand. I was given a massive amount of literature, booklets which I studiously read, so I could almost foretell what was going to happen. The only thing that has changed, that was quite significant, was that after the radiotherapy (pause) I didn't expect the radiotherapy to burn holes in my face'. [5,M,49]*

A few of the patients contracted post-surgical Methicillin-Resistant Staphylococcus Aureus (MRSA) and felt particularly anxious and uninformed. This was emphasised by one woman who described her distress at the lack of information:

> *'It was a nightmare in that nobody could tell you it, would tell you anything. And everybody was embarrassed about it... Somebody had forgotten to tell the anaesthetist that I had MRSA and there was all this kerffufle whilst they sorted that out'. [11,F,63]*

Another respondent reported miscommunication between her consultant and her understanding leading to uncertainty and fear. Moreover, although this respondent felt articulate enough to ask questions she expressed her lack of ability to do so out of fear:

> *'...it was another surgeon who looked at me and kinda went and said to me "well" and it was kind of chilling, "there's nothing we can do for you".... I really couldn't bring myself to ask like, "nothing at all to save my life or nothing with the reconstruction?" It wasn't made clear to me what was happening....I didn't have the resources to ask it'. [13,F,47]*

4.4.3.3 Timing of information

The lack of specific information or 'missing' information appeared to be related to the timing of information. Previous quotes have demonstrated that not all patients wanted detailed information at all stages of the illness, however, one respondent suggested that patients should have full knowledge of all possible side-effects and outcomes of treatment, prior to treatment, regardless of the anxiety this may provoke. The same respondent later mentioned that not knowing the full facts when complications arose was a major source of anxiety for him:

> *'...the times when things were going wrong and nobody was telling me were the times that I became anxious, agitated and concerned...' [5,M,49]*

This was further emphasised by a couple of respondents who considered that the lack of information or clarity stemmed from a 'knowledge gap' *'between a full understanding of what's going to happen to you and what information can convey'. [12,F,59]* . This was perceived to be caused by two factors, namely, the lack of time between diagnosis and treatment and the fact that traumatic experiences are indescribable until they've been experienced (likened to childbirth by a couple of women). The shock of diagnosis and the lack of time to assimilate the information were highlighted thus;

> *'At that time, when they've just told you, you have cancer and you're just about to have major surgery, you're not really listening...your mind's not on it'. [3,M,56]*

and;

> *'It was all carefully explained but it doesn't really register in the short time you have to think about it. You're trying to cope with a lot of information and you're not feeling very well'. [12,F,59]*

4.5 DISCUSSION

The findings from this qualitative study give increased insight into how pre- and post-treatment expectations in a sample of head and neck cancer patients are derived in part from information

received throughout the pre-treatment and subsequent recovery process. Respondents described expectations reflecting two sub-themes relating to: 'specific' expectations centred around: side-effects; aesthetic aspects of treatment and the recovery process; and 'global' expectations regarding the whole cancer experience. Favourable experiences were underpinned by expectations being surpassed. A large proportion of patients described the whole experience as being worse than they had expected. This was highlighted by a sense of 'enormity' about the treatment they had undergone and the recovery process, but also due to unexpected complications from treatment.

This pilot study also highlighted the individual nature of the information giving process, whereby many patients did not want too much detailed information about their illness and treatment, especially at the early stages between diagnosis and treatment, yet many respondents required a detailed breakdown of all the possible complications and variables associated with the recovery process. These differences in requirements may have been due to differences in personality and/or coping strategies between patients. Research has indicated that stable individual differences exist between patients' tendencies either to seek or to avoid potentially stressful information about cancer and other threatening medical procedures. Miller (1992) proposed that people react to health threats by coping in one of two ways. Either by trying to avoid or minimize obtaining stressful information and by distracting themselves from threatening information (*blunting* coping style) or by attending and scanning for threat relevant information about aversive medical events and rehearsing and amplifying them cognitively (*monitoring* coping style) (Miller, 1992; Miller, 1997). Tentative support for these coping styles was evidenced in the present study whereby some patients explicitly stated that they had not wanted to know in detail pre-operatively what was going to happen to them, as exemplified by; *'I only needed to know what was needed to be known. Because if I'd had too much information you would have found me in the corner with a vodka bottle'* and *'there's a limit to how much one can take in actually on something like this and how much you can actually cope with..'* Although the level of information

actually received by 'blunters' in this sample may have been less than for 'monitors', they tended to be more satisfied with the amount of information they had received, which is also supported by the literature (Steptoe & O'Sullivan, 1986). In contrast, those with a 'monitoring' coping style tended to be generally less satisfied with the standard amount of information and communication with the staff which has been previously demonstrated in other medical contexts (Miller, Brody, & Summerton, 1988; Steptoe et al., 1986). The data from the interviews also indicated that there was probably a dynamic relationship between a patient's need for information, expectations and coping. Modifying this cycle by intervention either at the informational level or through targeting specific coping strategies may influence patients expectations.

Patients' understanding and expectations regarding the actual treatment and recovery are likely to be influenced by information received from a range of health care professionals and patients they come into contact with. Patients value the expertise that the treating staff have, therefore they are essential in influencing patient's understandings. However, not surprisingly, contradictory information was a source of anxiety for a few patients in our study.

The role of information has previously been investigated in relation to a range of outcomes after treatment for head and neck cancer. Perceptions of adequate information from specialists were found to be predictors of positive rehabilitation outcomes in laryngectomy patients treated 2-6 years previously (De Boer et al., 1995). Similarly, satisfaction with information provided shortly before the end of radiotherapy was found to be a significant predictor of QoL in nasopharyngeal cancer patients 4 months later (Yu et al., 2001). (See Chapter 2 for more information about this study). The relationship between information and QoL has not been found to be straightforward. Kreitler et al., (1995) concluded from a study of 55 head and neck cancer patients that 'the psychosocial effects of the information the patient has at his or her disposal about the disease and its prognosis are greater than the effects of the severity of

disease per se' (Kreitler, Chaitchik, Rapoport, & Algor, 1995). This suggests that the psycho-social effects of the disease and treatment are not necessarily direct functions of disease severity but are mediated by the meanings the patient assigns to the disease and the total situation. Information is a major determinant of the meanings assigned along with the cognitive representation of a health threat. However, Kreitler et al., found that the effects of providing information were in some respects beneficial and in others detrimental from a psychological point of view (Kreitler et al., 1995). Our study also found that for some people, too much information meant that they were unable to cope with the health threat due to strong feelings of anxiety and fear. Although we did not seek to investigate the role of information on subsequent QoL or mood in our study, the evidence suggests that pre-treatment information is relevant to post-treatment adaptational processes/rehabilitation and these could be mediated by the individual's expectations. Indeed, as Calman proposed in 1984, QoL should be considered 'the extent to which our hopes and ambitions are matched by experience'. He argued that to improve QoL, health care should 'narrow the gap between a patient's hopes and expectations and what actually happens' (Calman, 1984b). Through tailoring information to the individual, the mismatch between unrealistic expectations and experience could be narrowed thus potentially improving outcome.

This study highlighted that patients' needs were frequently not being met. This is consistent with a report by The National Cancer Alliance (National Cancer Alliance, 2002), who highlighted through discussions with a focus group that although some patients had received written information, this was inadequate for their needs. A study by Edwards (1998), also highlighted the lack of satisfaction regarding information giving. It was suggested that patients wanted to have more information about the impact of their treatment and about different treatment options rather than details of the operation.

Many extraneous factors contribute to the information giving process (such as the time available to the patient, the presence of a multidisciplinary team, patient or clinician factors etc). However, many patients would like to be provided with written information and explanations about their treatment, advice on how to manage the effects of the treatment on their daily lives and adequate preparation prior to discharge from hospital. Written information is especially pertinent in cases where the patient is being subjected to 'too much information' around the time of diagnosis. It may even be feasible to provide the patient with a tape recording of early consultations to listen to at a time appropriate to them. Information about the late onset of symptoms (particularly with radiotherapy) should be provided on a written basis as contact with the relevant health care professional may not be feasible after treatment has ended.

Evidence, involving patients with other illnesses, suggests that pre-treatment expectations can have an influence on post-treatment outcomes in both a negative and positive way. For example, Iversen et al (1998), found that patients having surgery for lumbar spinal stenosis who had ambitious pre-surgery expectations for physical functioning were more likely to have improved function and satisfaction 6 months later (Iversen et al., 1998). Conversely, having unmet expectations regarding outcome (e.g. high expectations regarding pain relief) resulted in worse perceptions of outcome, such as more pain and less satisfaction with pain relief post-surgery. This highlights the importance of patients to have an optimistic stance regarding outcomes but without expectations being unduly unrealistic.

Research on lay experiences of illness has found that coming to terms with an illness event involves patients interpreting why the event has happened, how it can be further prevented and how its effects can be overcome (Bury, 1991). This process may be better understood by applying a framework such as Leventhal's Self-Regulatory Model (SRM) (Leventhal et al., 1980). A recent novel study by McCarthy et al., (2003) illustrated that the SRM proved a useful

theoretical framework with which to test the predictive value of pre-operative expectations in recovery from oral surgery (McCarthy et al., 2003). The SRM proposes that people organise cognitions regarding their health threat along five coherent themes; symptom identity, timeline; cause; consequence and control/cure (see chapter 3 for a detailed description of this approach). The model suggests that these five aspects may influence an individual's outcome from treatment such as surgery. McCarthy et al. (2003) found that pre-operative expectations (expectations regarding the five aspects outlined above) predicted symptom severity, psychological distress, speed of return to work and healing ratings seven days later.

Extensive research indicates that psychological preparation for surgery can improve patients' ability to recover from major surgery. These positive outcomes are more likely to reflect a complex set of processes involving information, the patient's emotional reactions to surgery and the subsequent perceptions of the underlying medical condition and treatment. According to the SRM, threat appraisal and the emotional distress it generates can be reduced by providing the patient with information that fosters an accurate representation of the surgical procedure and its effects, as well as information describing cognitive and behavioural strategies for coping (Contrada, Leventhal, & Anderson, 1994). Pre-surgical interventions based on self-regulatory theory have tended to focus on conveying two types of information to the patient, *procedural* and *somato-sensory* information (Contrada et al., 1994). Procedural information typically involves information about when and where procedures will occur accompanied by a discussion of the purpose of each aspect of the procedure. This is designed to add to the patient's disease representation or schema and serves to minimise the threat by reducing uncertainty. Somato-sensory information focuses on what sensations or symptoms the operation will produce and how these can be distinguished from the disease and the emotional reactions likely to be experienced. This more subjective information provides the patient with a script describing the internal sequence of somato-sensory and emotional events in order to reduce uncertainty and worry. However, more relevant to patients undergoing treatment to the

head and face, are concerns about the aesthetic outcome and the subsequent threat this poses to their sense of 'self-identity'. These considerations along with information on coping strategies for managing an altered appearance could perhaps be incorporated into interventions based on the SRM model in parallel with procedural and sensory information.

4.5.1 Limitations

Regarding the potential limitations, the data gained from the present study may be biased towards patients who have coped relatively well since diagnosis and who return for review visits. The majority of the patients had speech impediments to various degrees. This provided difficulty with transcribing, however, with careful listening and transcription shortly afterward conducting the interviews, this was not a problem, excluding one male case which combined with extraneous background noise, had to be discarded. The sample of patients interviewed were not representative of a typical sex ratio expected with HNC and this has to be acknowledged as a limitation of using a convenience sample. Although the nature of qualitative research is not to provide generalisable data, and the aim of the study was to explore patient expectations regarding recovery and outcome, in an area such as HNC where there are clear gender implications of having a disease that impacts aesthetically, a more representative sample may have provided different results.

The patients interviewed were at different periods of recovery, which provided a range of retrospective accounts. Patients were generally more upset when in the first stages of adjustment and patients having a longer period of recovery may have forgotten the pre-treatment expectations they had. A few patients did become upset during the interview although all refused to terminate the interview, many verbalising that they weren't upset per se but were just experiencing a cathartic emotional release as many had not felt able to express their emotions, especially regarding disappointments with recovery, previously.

More pertinent to qualitative research is the issue of introducing biases into the data. This can occur at the time of the interview due to the person interviewing, whilst interpreting the data or even due to variables such as the time of interview, the interview room and interruptions by other staff. A more linear approach to data analysis was adopted in terms of analysing the data after all the interviews had been conducted which could also be considered a limitation of the study. However, the intention was to elicit the patient's perspective before forming a framework and therefore introducing any biases into the data, before all the interviews had been conducted.

In conclusion, this pilot study produced a rich amount of material about the types of expectations individuals with HNC had at various stages of their treatment and recovery. Large variations were revealed between patient expectations and the actual experiences that were described. Expectations, both global and specific, seemed to be derived in part from the information received. Satisfying patients' needs for information has important implications for patient outcome. Reducing the uncertainty pre-treatment and narrowing the gap between expectation and actual experience may reduce feelings of depression and anxiety, as a result of experiencing unexpected negative events. This could easily be achieved by providing more written information on topics of importance to patients on a timely basis. Further research would be needed to explore the relationship between the fulfilment of pre-treatment patient expectations and patient outcomes, such as QoL or depressive symptoms, post-treatment.

CHAPTER 5

METHODOLOGY

This chapter describes the general methods used in this thesis. The specific details of how these methods were implemented, why particular measures were chosen and how the data were analysed, are presented in the relevant chapters.

The chapter is divided into two parts: Part 1 consists of a summary of the methods used for the main longitudinal study and additional cross-sectional study, including information about study design, participants and measures used. Part 2 consists of a description of the methods used to develop and psychometrically test a novel measure to assess patient's satisfaction with information about cancer treatment: the Satisfaction with Cancer Information Profile (SCIP).

5.1 PART 1: GENERAL METHODS

5.1.1 Prospective outcome study

5.1.1.1 Study design

A prospective (repeat measures) design was chosen for the main study in order to address the main research questions regarding the nature and processes associated with adaptation and QoL over time. The method of data collection was by questionnaire (with additional data supplied from hospital records with permission).

Newly diagnosed head and neck cancer patients were recruited into the study (see section 5.1.1.2 for exact procedural details). Assessments were made at three time points: at baseline (after diagnosis but before cancer treatment started), one month after the end of treatment (Time 2), and six-eight months post-treatment (Time 3). Due to the time constraints of recruiting patients with a relatively rare disease into a longitudinal study, follow-up was completed at approximately eight months. Follow-up was terminated at 8 months, at

recurrence of disease, on entering palliative care or death. All clinical information was derived from patient's medical records.

5.1.1.2 Procedure

Potentially eligible patients were first identified from attending head and neck cancer clinics at Guy's and St Thomas' Hospitals, London, The Royal Sussex County Hospital, Brighton, University College London Hospital, London and The Royal Marsden Hospital, London. Patients currently under investigation or referred from other hospitals after histological confirmation of cancer were advised of their diagnosis in these clinics. Patients were not directly approached on their first visit, although some were informed by the consultant that various research studies were being conducted in the clinic and that they would be approached at a later date. Eligible patients at Guy's and St Thomas' Hospitals were also identified at the weekly multi-disciplinary meetings (MDM) for head and neck oncologists, ear, nose and throat (ENT) specialists and members of the treating team, such as, dieticians, dentists, specialist HNC nurses, house officers, registrars and speech therapists. Any queries as to the suitability of potential participants could then be discussed with the relevant consultant if the patient hadn't been assessed in the clinic initially by the researcher (see section 5.1.1.3 for inclusion criteria).

Once patients were identified, participants were subsequently invited to take part in 'a study assessing patients' views about their cancer and treatment'. After being informed of what involvement would be required, participants were given a patient information letter (appendix V), a consent form (appendix VI), a questionnaire pack (appendix VII), and postage paid envelope in which to return the questionnaire. It was emphasised that responses would be confidential and anonymous and that no members of the treating team would have access to individual questionnaires. As the content of the questionnaire was quite lengthy, participants completed the questionnaires at home and returned them by post or handed them in on their

next visit[3]. Participants were also advised that assistance was available if required. Where patients had given their consent but did not return the questionnaire at baseline, patients were either given a verbal reminder at subsequent clinic attendances prior to treatment, or phoned, and given further questionnaires if required.

5.1.1.2.1 Follow-up assessment

At follow-up assessments one month after the end of treatment and at six-eight months after the end of treatment (T2 and T3), a letter, a questionnaire and a pre-paid reply envelope were sent out by post. If patients did not respond within two weeks, a further questionnaire was sent out, which was followed up with a reminder phone-call if required. Follow-up assessment was discontinued if the patient required further treatment for a recurrence or patients entered a palliative phase.

5.1.1.3 Participants

Patients with a histologically confirmed diagnosis of cancer of the head or neck were eligible for inclusion in this study. However, patients were not eligible for recruitment if any of the conditions below were met:

- Under eighteen years of age
- Previous head and neck cancer diagnosis (not dysplasia)
- No known primary tumour
- Any mental / cognitive impairments e.g. Alzheimers disease or psychiatric conditions
- Undergoing treatment with palliative intent
- Those who had started treatment (for the current diagnosis) at another hospital prior to referral to the recruiting hospitals
- Metastatic disease in other parts of body (excluding neck nodes).
- Diagnosis of Lymphoma.

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[3] Occasionally, participants were recruited as in-patients if they required direct medical intervention prior to starting cancer treatment. Therefore, questionnaires were completed during their stay on the ward, which were then collected by the researcher.

- Those without a sufficient understanding of English[4]

5.1.1.3.1 Multi-centre study patient recruitment

Table 5.1 presents the breakdown of patients recruited from each recruitment site. Recruitment at Guy's and St Thomas' started on the 1st July 2003 and thus the majority (70%) of the recruited patients were primarily treated at either of these hospitals. Recruitment at The Royal Sussex County Hospital started in late August 2003 and a further seventeen patients (21%) were recruited. Despite recruitment start dates of September 2003 only six (7%) and two patients (2%) from The Royal Marsden Hospital and University College London Hospitals respectively, were recruited. The recruitment period of ten months finished at the end of May 2004.

Multi-centre studies are considered to be more desirable as they enhance the generalisability of the findings outside the treatment centre (Bowling, 1997). However, it is recognised that in the present study, no sampling procedure was adopted due to the difficulty recruiting sufficient patients.

Table 5.1: Breakdown of patients eligible for recruitment from each site

Hospital	No. of patients eligible	No. of patients recruited	Response rate
Guy's & St Thomas' Hospitals	79	57	72%
The Royal Marsden Hospital*	6	6	N/A
The Royal Sussex County Hospital	21	17	81%
UCLH*	2	2	N/A

* No approached rather than number eligible.

[4] Unfortunately, this study could not support the services of a translator and therefore patients who could not read and write English were not eligible. It is acknowledged that this severely limits the cross-cultural generalisability of this study.

Results from Guy's and St Thomas' hospitals have been combined as some consultants see patients at either sites and both provide treatment for the same catchment area. The response rate based on the three main recruitment sites (Guy's & St Thomas' Hospitals, and The Royal Sussex County Hospital) were patients were recruited systematically was 76% overall.

The clinical and socio-demographic characteristics of responders versus non-responders can be found in the results. Likewise, the numbers of patients retained at follow-up, with details on survival/ drop out rates are described within the relevant chapter (chapter 8).

5.1.1.3.2 Difficulties with patient recruitment

During the recruitment phase, three main problems arose which affected patient recruitment. Firstly, the head and neck oncology services at Guy's, King's and St Thomas' Hospitals underwent a period of reorganisation and merging. This meant that clinics that were originally run over three sites on different days eventually took place at Guy's Hospital at the same day and time. This had advantages and disadvantages. Originally, recruiting from the three separate sites meant the researcher could see all patients firsthand and explain participation in the study face to face. However, there was no central list of all patients being seen and inevitably some eligible patients were not identified and contacted in time (i.e. prior to starting treatment). After the merger, services were streamlined into one head and neck cancer service thus, only one clinic could actually be attended by the researcher which reduced the number of patients seen face to face. However, patients could be identified at the MDM which included patients seen by all consultants. Patients identified this way were contacted by post. This was not as successful as firsthand contact with the patient.

Secondly, The Royal Marsden Hospital (RMH), London was chosen in order to increase patient recruitment. The RMH is another of the major cancer treatment centres in the South East of England. Recruitment was overseen by a specialist HNC research nurse which was a

condition of local research ethics approval. Despite initial enthusiasm from the research nurse and consultants, two further clinical cancer trials involving HNC patients commenced. This lead to an overload of duties on the research nurse but more importantly, eligible patients were initially entered into in-house trials and staff felt that patients were overburdened with too many research studies. Unfortunately, despite repeat enquiries into recruitment, there was a general reluctance to inform us of the situation until quite late on. Recruitment was eventually stopped and therefore was not as successful as originally anticipated.

In addition, The Royal Sussex County Hospital was approached in the early stages of planning in order to bolster recruitment rates, but unfortunately, LREC approval took approximately six months to gain.

A third, albeit minor problem with recruitment, centred around the definition of what a 'new cancer case' was. Patients are considered to be new patients if they are diagnosed with a 'new primary' cancer, even if they have had HNC in the past. These incidences are considered to be recurrences by some specialists, but if a cancer is diagnosed in a different head and neck site to the original cancer, it is recorded and treated as a new cancer. The patient is recorded as a new patient in the notes or database, especially if the patient was originally treated at a different hospital. Therefore, it was apparent quite quickly that there were not as many eligible patients as originally anticipated. It was decided that these patients would not be eligible for inclusion in the current study (unlike other studies where this is not made explicit), as these patients would have undergone some form of cancer treatment and would have prior experience of a cancer diagnosis with the associated emotional reactions and representations.

Another important issue affecting both recruitment and follow-up assessment was the timing of the start of treatment and the actual length of treatment. Treatment was commenced as soon as possible with waiting times of approximately two to three weeks for surgery and

approximately 4-6 weeks for radiotherapy (RT), depending on the time of year. Timing was particularly pertinent with surgical patients whereby the period between initial diagnosis and treatment was sometimes very short. In cases where patients were posted the questionnaire, there was very little time for the patient to consider participating and completing the questionnaire. Many patients that refused to participate replied that they were too busy putting their lives in order in the short time left to take part. A few patients were contacted as in-patients due to this time constraint. Likewise, it was also not anticipated that the period of treatment would be so lengthy. In cases where patients also required post-surgical RT, a period of wound healing would be required of typically four to six weeks (if no complications) and then a further period of four to six weeks of RT. This meant that it was not unusual for a period of four and half months to elapse between diagnosis and T2 assessment. This resulted in a recruitment period that was quite short in order to complete all assessments within the time limits.

5.1.2 CROSS-SECTIONAL STUDY OF POST-TREATMENT ADAPTATION

5.1.2.1 Study design

This cross-sectional questionnaire based postal study was conducted with three main intentions. Firstly, due to the relatively short period of follow-up assessment in the prospective study, more data was required to explore adaptation issues over a longer period since treatment. This study aimed to assess factors, which contributed to emotional and cognitive adaptation after treatment for HNC. Secondly, in order to examine wider issues of adaptation, pertaining to life satisfaction, a different questionnaire was required. Therefore, a separate sample of post-treatment patients was selected who were not part of the main study. In addition, this was a comparison study, whereby three other samples were collected in order to control for factors such as the effects of having surgery, or coping with a cancer diagnosis. The procedures for recruiting the three additional control samples are described in sections 5.1.2.2.2 to 5.1.2.2.4.

5.1.2.2 Procedure

5.1.2.2.1 Identification of main sample of patients treated for malignant tumours of the head

Details of all surviving patients from one oral surgeon (MM) at the Department of Oral Surgery, at Guy's Hospital were collected from the Head and Neck Cancer Database (INFOFLEX). Patients were eligible if they were at least 6 months post treatment (to allow time for physical healing) and had been diagnosed and treated for carcinoma of the head region, with no active recurrences or further treatment planned. This database contains details of patients treated over the last ten years (approximately).

5.1.2.2.2 Identification of patients treated for malignant tumours of the glottis/larynx (Throat cancer group)

Patients within this sample were recruited from two hospitals. The original aim of this comparison group was to recruit early stage (stage 1 or 2) patients diagnosed with a malignant tumour of the neck (larynx or glottis), who had been treated with radiotherapy only. This was to provide a cancer comparison group for the effects of surgery. Early stage cancers of the larynx and glottis are generally only treated with radiotherapy, hence the rationale for only selecting early stage carcinomas. In addition, these patients could also have provided a comparison for the effects of cancer stage on adaptation. Hospital records (hand written) from the Department of Radiotherapy at Guy's Hospital were hand searched for details of patients treated for early stage (T1 or T2) tumours in the last ten years (there is no electronic database containing the treatment details of patients treated up to ten years ago). Patients identified from these records were then checked against the departmental RT database for the hospital number, which was then checked on PIMS (Guy's Hospital Trust patient database) for patient survival status and address for mailout. This process was conducted by a senior house officer. At each stage of the process, some patient's records could not be identified and thus the final patient sample was greatly reduced.

Due to this and in order to achieve a larger patient sample, we also recruited similar patients treated with radiotherapy for early stage cancer of the larynx/glottis from The Royal Marsden Hospital (LREC amendment to protocol 2300, dated 27/04/04). A list of patient's names and addresses was provided by a RMH Consultant Oncologist from the departmental database. Unfortunately, it was subsequently found that nearly half of the recruited sample had also undergone surgical intervention in addition to radiotherapy. Therefore, the main intentions behind recruiting this comparison group could not be fully realised. Instead, this sample was used as a comparison group for the effect of treatment for cancer with less severe aesthetic consequences to the facial region than a head cancer.

5.1.2.2.3 Identification of patients treated for benign salivary gland conditions

Participants within this sample consisted of patients treated by one oral surgeon (consistent with the head cancer patients) for a benign tumours of the salivary glands requiring surgery. Inclusion criteria were that all patients should have been treated surgically and that the final histological diagnosis was benign.

5.1.2.2.4 Age and gender matched non-clinical sample

Participants were recruited from the community in the UK using a market research agency (Research Initiatives Ltd). This sample was purposefully matched with the sample of recruited head cancer patients on factors of age and gender. Thus, this sample was collected after the main sample had been recruited. The market research agency was requested to recruit 115 people in the age range of 37 to 95 years old with a ratio of 2 males to every female to match the gender ratio in the main sample. All participants recruited through the market research agency were given a £2 gift voucher as recompense for their time and effort in completing the questionnaire.

All participants (excluding the age and gender matched non-clinical sample) were posted a patient information sheet (e.g. Appendix VIII), two consent forms (Appendix IX), a reply paid envelope and the questionnaire consisting of the four measures detailed in section 9.3.4. The questionnaire pack administered in this study was kept to a minimum (four brief questionnaires) in order to avoid placing excessive demands on patients who were not approached face to face.

Ten additional questions asked about socio-demographic factors, type of treatment (choice of four categories: surgery, radiotherapy, chemotherapy and other), time since last being treated, whether patients were still undergoing treatment, and whether any further illnesses or diseases had been diagnosed since being treated for the particular condition of interest. Participants recruited into the normative sample were asked whether they had suffered from any major illnesses / diseases in the last ten years. Patients found to be still undergoing treatment for their condition were excluded from analysis. After three weeks, all non-responding patients were sent a further reminder letter, additional questionnaire, consent forms and reply-paid envelope in order to encourage participation. In order to establish more accurate response rates, the survival status of non-responders were investigated by a research nurse. Where listed in the medical records, the patient's general practitioner was phoned and asked whether they had a record of the patient's current survival status or whether the patient's address was different to the one listed in our hospital medical records. In order to protect the patient's privacy, the new address was not requested and the patient was not contacted again.

5.1.2.2.5 Infoflex Database

Prospective information about all cases treated by one consultant (MM) from the Department of Oral Surgery is entered onto a database designed and made by InfoFlex. Data that are recorded on this database include patient details, histological, medical and treatment details. The non-medical data contained on this database are primarily collected from departmental

Senior House Officers when the patient is first clerked in the Head and Neck Cancer Clinic. Thus some of the data is derived from patients and house officers and the reliability of the data cannot be commented on.

5.1.2.3 Participants

One hundred and ninety-two patients with cancer of the head were originally identified from the database as fulfilling the criteria. Of these, thirty were later confirmed to have died and twenty-three were not contactable (were abroad or confirmed to have moved from the address supplied). Only two patients refused to participate. One hundred and fifteen patients returned completed questionnaires. The response rate calculated from those potentially contactable was therefore 84%. A breakdown of the clinical and socio-demographic characteristics of the responders and non-responders (age, gender and cancer staging) can be found in chapter 9.

Ninety-seven eligible patients who had been treated for a benign salivary gland condition were eligible for inclusion in this study. Four were confirmed as deceased, and twelve were not contactable. Forty-seven participants returned questionnaires, giving a response rate of 58%.

5.1.2.4 Tumour staging

The staging of head and neck carcinoma has changed little in the past decade (Forastiere, Koch, Trotti, & Sidransky, 2001). Traditional staging methods are weak and systems that use rating methods by means of the standard tumour-node-metastasis (TNM) staging method are commonly used (American Joint Committee on Cancer, 2002). The following TNM definitions for each of the main sites are originally derived from The National Cancer Institute via www.cancerindex.org.

5.1.2.4.1 TNM definitions for cancer of the oropharynx

Primary tumour (T)

TX: Primary tumour cannot be assessed

T0: No evidence of primary tumour

Tis: Carcinoma *in situ*

T1: Tumour 2 cm or less in greatest dimension

T2: Tumour more than 2 cm but not more than 4 cm in greatest dimension

T3: Tumour more than 4 cm in greatest dimension

T4a: Tumour invades the larynx, deep/extrinsic muscle of tongue, medial pterygoid, hard palate, or mandible. T4b: Tumour invades lateral pterygoid muscle, pterygoid plates, lateral nasopharynx, or skull base or encases carotid artery

Regional lymph nodes (N)

NX: Regional lymph nodes cannot be assessed

N0: No regional lymph node metastasis

N1: Metastasis in a single ipsilateral lymph node, 3 cm or less in greatest dimension

N2: Metastasis in a single ipsilateral lymph node, more than 3 cm but not more than 6 cm in greatest dimension, or in multiple ipsilateral lymph nodes, none more than 6 cm in greatest dimension, or in bilateral or contralateral lymph nodes, none more than 6 cm in greatest dimension. N2a: Metastasis in a single ipsilateral lymph node more than 3 cm but not more than 6 cm in greatest dimension. N2b: Metastasis in multiple ipsilateral lymph nodes, none more than 6 cm in greatest dimension. N2c: Metastasis in bilateral or contralateral lymph nodes, none more than 6 cm in greatest dimension

N3: Metastasis in a lymph node more than 6 cm in greatest dimension

Distant metastasis (M)

MX: Distant metastasis cannot be assessed

M0: No distant metastasis

M1: Distant metastasis

5.1.2.4.2 TNM definitions for cancer of the larynx

Primary tumour (T)

TX: Primary tumour cannot be assessed

T0: No evidence of primary tumour

Tis: Carcinoma in situ

5.1.2.4.2.1 Site: Supraglottis

T1: Tumour limited to one subsite* of supraglottis with normal vocal cord mobility

T2: Tumour invades mucosa of more than one adjacent subsite* of supraglottis or glottis or region outside the supraglottis (e.g., mucosa of base of tongue, vallecula, medial wall of pyriform sinus) without fixation of the larynx

T3: Tumour limited to larynx with vocal cord fixation and/or invades any of the following: postcricoid area, pre-epiglottic tissues, paraglottic space, and/or minor thyroid cartilage erosion (e.g., inner cortex)

T4a: Tumour invades through the thyroid cartilage, and/or invades tissues beyond the larynx (e.g., trachea, soft tissues of the neck including deep extrinsic muscle of the tongue, strap muscles, thyroid, or oesophagus). T4b: Tumour invades prevertebral space, encases carotid artery, or invades mediastinal structures.

Subsites include the following: ventricular bands (false cords); arytenoids; suprahyoid epiglottis; infrahyoid epiglottis; aryepiglottic folds (laryngeal aspect)

5.1.2.4.2.2 Site: Glottis

T1: Tumour limited to the vocal cord(s) (may involve anterior or posterior commissure) with normal mobility

T1a: Tumour limited to one vocal cord

T1b: Tumour involves both vocal cords

T2: Tumour extends to supraglottis and/or subglottis, and/or with impaired vocal cord mobility

T3: Tumour limited to the larynx with vocal cord fixation and/or invades paraglottic space, and/or minor thyroid cartilage erosion (e.g., inner cortex)

T4a: Tumour invades through the thyroid cartilage and/or invades tissues beyond the larynx (e.g., trachea, soft tissues of neck, including deep extrinsic muscle of the tongue, strap muscles, thyroid, or oesophagus). T4b: Tumour invades prevertebral space, encases carotid artery, or invades mediastinal structures

5.1.2.4.2.3 Site: Subglottis

T1: Tumour limited to the subglottis

T2: Tumour extends to vocal cord(s) with normal or impaired mobility

T3: Tumour limited to larynx with vocal cord fixation

T4a: Tumour invades cricoid or thyroid cartilage and/or invades tissues beyond the larynx (e.g., trachea, soft tissues of neck, including deep extrinsic muscles of the tongue, strap muscles, thyroid, or oesophagus). T4b: Tumour invades prevertebral space, encases carotid artery, or invades mediastinal structures

Regional lymph nodes (N)

NX: Regional lymph nodes cannot be assessed

N0: No regional lymph node metastasis

N1: Metastasis in a single ipsilateral lymph node, 3 cm or less in greatest dimension

N2: Metastasis in a single ipsilateral lymph node, more than 3 cm but not more than 6 cm in greatest dimension, or in multiple ipsilateral lymph nodes, none more than 6 cm in greatest dimension, or in bilateral or contralateral lymph nodes, none more than 6 cm in greatest dimension. N2a: Metastasis in a single ipsilateral lymph node more than 3 cm but not more than 6 cm in greatest dimension. N2b: Metastasis in multiple ipsilateral lymph

nodes, none more than 6 cm in greatest dimension. N2c: Metastasis in bilateral or contralateral lymph nodes, none more than 6 cm in greatest dimension. N3: Metastasis in a lymph node more than 6 cm in greatest dimension

Distant metastasis (M)

MX: Distant metastasis cannot be assessed

M0: No distant metastasis

M1: Distant metastasis

5.1.2.4.3 TNM definitions for cancer of the Hypopharynx

Primary tumour (T)

TX: Primary tumour cannot be assessed

T0: No evidence of primary tumour

Tis: Carcinoma *in situ*

T1: Tumour limited to 1 subsite* of the hypopharynx and 2 cm or less in greatest dimension

T2: Tumour invades more than 1 subsite* of the hypopharynx or an adjacent site, or measures more than 2 cm but not more than 4 cm in greatest diameter without fixation of hemilarynx

T3: Tumour measures more than 4 cm in greatest dimension or with fixation of hemilarynx

T4a: Tumour invades thyroid/cricoid cartilage, hyoid bone, thyroid gland, oesophagus, or central compartment soft tissue (including prelaryngeal strap muscles and subcutaneous fat). T4b: Tumour invades prevertebral fascia, encases carotid artery, or involves mediastinal structures

*Subsites of the hypopharynx are as follows: Pharyngoesophageal junction (postcricoid area), extending from the level of the arytenoid cartilages and connecting folds to the

inferior border of the cricoid cartilage. Pyriform sinus, extending from the pharyngoepiglottic fold to the upper end of the oesophagus, bounded laterally by the thyroid cartilage and medially by the surface of the aryepiglottic fold and the arytenoid and cricoid cartilages. Posterior pharyngeal wall, extending from the level of the floor of the vallecula to the level of the cricoarytenoid joints.

Regional lymph nodes (N)

NX: Regional lymph nodes cannot be assessed

N0: No regional lymph node metastasis

N1: Metastasis in a single ipsilateral lymph node, 3 cm or less in greatest dimension

N2: Metastasis in a single ipsilateral lymph node, more than 3 cm but not more than 6 cm in greatest dimension, or in multiple ipsilateral lymph nodes, none more than 6 cm in greatest dimension, or in bilateral or contralateral lymph nodes, none more than 6 cm in greatest dimension. N2a: Metastasis in a single ipsilateral lymph node more than 3 cm but not more than 6 cm in greatest dimension. N2b: Metastasis in multiple ipsilateral lymph nodes, none more than 6 cm in greatest dimension. N2c: Metastasis in bilateral or contralateral lymph nodes, none more than 6 cm in greatest dimension

N3: Metastasis in a lymph node more than 6 cm in greatest dimension

Distant metastasis (M)

MX: Distant metastasis cannot be assessed

M0: No distant metastasis

M1: Distant metastasis

Final pre-treatment staging systems are all clinical, based on the best possible estimate of the extent of disease before treatment. The assessment of the primary tumour is based on inspection and palpation when possible, and by indirect mirror examination where possible.

The tumour must be confirmed histologically, and any other pathologic data obtained from a biopsy may be included. Additional radiographic studies may be included. As an adjunct to clinical examination, positron-emission tomography (PET) and magnetic resonance imaging (MRI) are universally accepted as vital tools for clinical staging. As pre-treatment staging is based on clinical data it may in some cases not be an accurate representation of the true size of the tumour.

Post-surgery pathological staging occurs after surgery and is sometimes provided on pathology reports. However, not all pathologists provide a TNM staging on their reports (e.g. RSCH) and patients that do not have surgery will not be provided with a final staging.

In this thesis a mixture of pre-and post-treatment staging was used depending on the circumstance. To provide a simple measure of tumour size/severity, for comparative and statistical purposes, the *overall stage* was used and not the actual TNM stage for continuity across cancer sites (see Table 5.2).

Table 5.2: General summary of overall staging based on TNM system (American Joint Committee on Cancer, 2002)

	NO	**N1**	**N2a**	**N2b**	**N2c**	**N3**	**M1**
T1	Stage 1	Stage 3	Stage 4a	Stage 4a	Stage 4a	Stage 4b	Stage 4c
T2	Stage 2	Stage 3	Stage 4a	Stage 4a	Stage 4a	Stage 4b	Stage 4c
T3	Stage 3	Stage 3	Stage 4a	Stage 4a	Stage 4a	Stage 4b	Stage 4c
T4	Stage 4a	Stage 4a	Stage 4a	Stage 4a	Stage 4a	Stage 4b	Stage 4c

5.1.3 Ethical approval

Multiple research ethics committee (MREC) approval was not originally sought, as the intention was only to recruit from two trusts (King's College Hospital NHS Trust and Guy's &

St Thomas' Hospital Trust). In order to harness more recruits into the study and increase the likelihood of achieving the study aims, it was realised that more recruitment sites would have to be included. This was a gradual process and is reflected in the staggered patient recruitment from each of the sites.

Local Research Ethics Committee and Research & Development committee approval was granted from the following NHS Trusts: Guy's & St Thomas' Hospital Trust (ref: 02/03/07), King's College Hospital NHS Trust (ref: 02-03-053), Lewisham Hospital NHS Trust (ref: 03/08/01), The Royal Marsden NHS Trust (ref: 2300), Brighton and Sussex University Hospitals NHS Trust (ref: (B)03/10), University College London Hospitals NHS Trust (ref: 03/0263) Letters of approval can be found in Appendix X.

5.1.4 MEASURES

All the measures included in the questionnaire booklet are intended for self-administration. Not all of the measures detailed below were used at all time periods or with all of the study samples. For a list of which of these measures were used in each study refer to Appendix IV(b), and each specific chapter.

5.1.4.1 Outcome measures

The following well-used and validated measures were used to assess outcome in terms of standardised (traditional) HR-QoL[5].

[5] The British Association of Head and Neck Oncologists (BAHNO) Council recommends the adoption of the University of Washington Quality of Life questionnaire (Hassan et al., 1993; Rogers et al., 2002) as part of the minimum dataset (http://www.bahno.org.uk/bulletin.htm). It was decided not to use this questionnaire in the present thesis for a number of reasons. Firstly, from the literature review it can be seen that most European studies use the EORTC QLQ-C30 and, therefore, for comparison purposes it was decided that this would be the most appropriate. Secondly, for academic research the EORTC QLQ-C30 provides more detailed information on the patient's HR-QoL. However, for clinical audit, the UW-QoL is recommended, for ease of use for both clinicians and patients.

5.1.4.1.1 The European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 (version 3) and Head and Neck Module (H&N35)

Core questionnaire: QLQ-C30 (pages 406-407)

The EORTC QLQ-C30 is a well-known and validated questionnaire for use with general cancer patients (see chapter 2) (Aaronson et al., 1993). This core questionnaire was designed to be: 1) cancer specific, 2) multidimensional in structure, 3) appropriate for self-administration (i.e. brief and easy to complete), and 4) applicable across a range of cultural settings. The questionnaire consists of thirty items, with the first twenty-eight items scored on a four-point response scale coded 'not at all', 'a little', 'quite a bit' and 'very much'. The QLQ-C30 incorporates five functional scales (physical, role, cognitive, emotional and social), three symptom scales (fatigue, pain, and nausea and vomiting), and a number of individual items assessing symptoms commonly associated with cancer (dyspnoea, loss of appetite, insomnia, constipation and diarrhoea) and financial difficulties.

A global health status/QoL scale can be calculated, which consists of two items on a 7-point response scale, from, 1 = very poor to 7=excellent.

All of the scales and single item measures range in score from 0-100. A high score on a functional scale or global health status/QoL represents a high level of functioning, however, a high score for a symptom scale/item represents a high level of symptoms/problems. Version 3 is currently the standard version of the QLQ-C30.

Scoring procedure (Fayers *et al.*, 2001)

Firstly, the average of the items that contribute to each scale is calculated, this is the raw score.

Raw score (RS) = $(item_1 + item_2 + ...item_n)/n$

Secondly, the raw scores are linearly transformed to standardise them, so that scores range from 0-100.

Linear transformation

Functional scales = {1- ((RS-1)/range)} x100

Symptom = {(RS-1)/range} x100

Global health status/QoL = {(RS-1)/range} x100

Missing items

Missing items from multi-item scales were addressed by applying a method of imputation. If at least half of the items were completed from a subscale (or domain), it was assumed that the missing items had values equal to the average of the items completed. The equations under 'scoring procedures' for calculating scale scores were applied ignoring the missing items. Hence the above equations can be used whenever at least half the items are completed. For example, Role Functioning and Cognitive Functioning each contain 2 items and therefore these scales can be estimated whenever one of their constituent items is present. Physical Functioning requires at least 3 items completed from the 5 items. Using this method, none of the single-item measures can be imputed.

A note on missing data

The rules used above to deal with missing data have been exercised with caution. The number of items in a subscale that were originally missing was noted in order to indicate how much of the original data has been amended.

Head & Neck cancer module: QLQ-H&N35 (pages 408-409)

The head and neck cancer specific module QLQ-H&N35 (Bjordal *et al.*, 2000) is for use with HNC patients of varying disease stage and treatment modality (Bjordal & Kaasa, 1992; Bjordal *et al.*, 1994).

The module comprises 35 questions assessing symptoms and side-effects of treatment, social function and body image/sexuality. The module was developed according to the guidelines, and pre-tested on patients from countries in Europe and field tested in Norway, Sweden and The Netherlands and in a large cross-cultural study involving more than ten countries (Bjordal *et al.*, 2000). All items are scored on a 4-point response scale coded 'not at all', 'a little', 'quite a bit' and 'very much'. The H&N35 incorporates seven multi-item scales that assess pain, swallowing, senses (taste and smell), speech, social eating, social contact and sexuality. In addition there are also eleven single items. For all items and scales, high scores indicate more problems (in contrast to functioning scales of the core questionnaire).

An additional exploratory item was also added to this questionnaire in order to identify particular problems with arm and shoulder function commonly resulting from neck dissections. There is currently no item addressing this area in the EORTC QLQ-H&N35 module. The item was: 'Have you had any problems in the area of your shoulder/arm e.g. pain or mobility problems?' This item was presented with the same format as the previous H&N35 items (i.e. on a 4 point scale scored as above). This item was scored separately and therefore did not effect the scoring of the subscales.

Scoring procedure

The scoring procedure and handling of missing items are identical to those for the symptom scales and single items of the QLQ-C30.

5.1.4.1.2 SF-12 Health Survey (SF-12v2) (pages 410-411)

The SF-12 is a well known and validated multi-purpose short-form comprising 12 questions selected from the SF-36 Health Survey (Ware *et al*, 1996). Version 2of the SF-12 is currently the version of choice and for the following studies the standard version (4 week recall) was considered most appropriate for this study. The SF-12 produces an eight scale profile of health, comprising subscales of: Physical Functioning, Role Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role Emotional and Mental Health. Two aggregate scores of 'Physical Component Summary' (PCS) and 'Mental Component Summary' (MCS) can also be calculated. This version was chosen because of its improvement in precision from previous versions, in conjunction with a reduction in respondent burden.

Scoring procedures

Multi-item Scales

SF-12v2 items are scored so that a higher score indicates a better health state. For example, functioning items are scored so that a high score indicates better functioning and the pain item is scored so that a high score represents more freedom from pain. Items are scored in three steps: Firstly, items are recoded for 4 of the items. One item - General Health requires calibration, for which recoding values are given by the authors (Ware, Kosinski, Turner-Bowker, & Gandek, 2002).

After item recoding, a raw score is computed for each scale. This score is the simple algebraic sum of responses for all items in the same scale. This simple method is possible because items in the same scale have roughly equivalent relationships to the underlying health concept being measured and no item is used more than once. Therefore, it is not necessary to standardise or weight items.

The last step involves transforming each raw scale score to a 0-100 scale using the formula shown below.

$$\text{Transformed scale} = \left[\frac{\text{Actual raw score} - \text{lowest possible raw score}}{\text{Possible raw score range}} \right] \text{x100}$$

It is not recommended to derive an overall measure of health status from the responses to the 12 items, however, two aggregate scores of 'Physical Component Summary' (PCS) and 'Mental Component Summary' (MCS) can be derived in line with SF-36 scoring.

Component Summary Scales

Following the scoring of the eight scales as described above, scoring of the PCS and MCS measures involves three additional steps. Standardisation using British norms cannot be computed as UK scoring algorithms have not been developed for the SF-12v2 (private correspondence, Qualitymetric Inc., 2004). It was also recommended by Qualitymetric Inc. Scientific Support Unit, to use standard scoring algorithms derived from the 1998 general U.S population published in the manual regardless (Ware *et al.*, 2002). This is to ensure the results can be meaningfully compared with other published scales and values.

1) Standardisation of SF-12v2 scales (z scores)

A z-score for each scale is computed by subtracting the mean 0-100 score observed in the 1998 general U.S. population (Table 5.3) for each SF-12v2 scale score (0-100 scale) and dividing the difference by the corresponding scale SD (Table 5.3) from the general 1998 general U.S. population.

Table 5.3: 1998 general U.S. population means, standard deviations and 1990 factor score coefficients used to derive PCS and MCS scale scores, standard form

SF-12v2 Scale	Mean*	SD*	Factor score coefficients	
			PCS	MCS
Physical Functioning (PF)	81.18122	29.10558	0.42402	-0.22999
Role Physical (RP)	80.52856	27.13526	0.35119	-0.12329
Bodily Pain (BP)	81.74015	24.53019	0.31754	-0.09731
General Health (GH)	72.19795	23.19041	0.24954	-0.01571
Vitality (VT)	55.59090	24.84380	0.02877	0.23534
Social Functioning (SF)	83.73973	24.75775	-0.00753	0.26876
Role Emotional (RE)	86.41051	22.35543	-0.19206	0.43407
Mental Health (MH)	70.18217	20.50597	-0.22069	0.48581

*** The means and standard deviations for each SF-12v2 scale are based on the 0-100 scoring (i.e. the steps explained in the previous section)**

For example:

Physical Functioning_Z= (PF-81.18122) / 29.10558

2) Aggregation of scale scores, standard form

Computation of the aggregate *physical summary score* consists of multiplying the z-score of each SF-12v2 scale by its respective physical factor score coefficient and summing the eight products. Similarly, an aggregate *mental summary score* is produced by multiplying the z-score of each SF-12v2 scale by its respective mental factor score coefficient and summing the eight products.

Formulas for aggregating scales in estimating aggregate physical and mental summary scores:

AGG_PHYS = (PF_Z*.42402) + (RP_Z*.35119) + (BP_Z*.31754) + (GH_Z*.24954) + (VT_Z*.02877) + (SF_Z*-.00753) + (RE_Z*-.19206) + (MH_Z*-.22069)

AGG_MENT = (PF_Z*-.22999) + (RP_Z*-.12329) + (BP_Z*-.09731) + (GH_Z*-.01571) + (VT_Z*.23534) + (SF_Z*.26876) + (RE_Z*.43407) + (MH_Z*.48581)

3) Transformation of summary scores, standard form

Transformation of the aggregate physical and mental summary scores to norm based (50, 10) scoring is achieved by multiplying each aggregate summary score from step 2 by 10 and adding the resultant product to 50, using the formulas below:

Formulas for t-score transformation of summary scores:

Transformed Physical (PCS) = 50 + (AGG_PHYS*10)

Transformed Mental (MCS) = 50 + (AGG_MENT*10)

Missing items

If a respondent was missing any one of the eight SF-12 scales, summary scales were not calculated.

As the above measures do not take into account any judgement of the relative importance of areas affected by the cancer and treatment, an individualised (patient centred) measure of the impact of head and neck cancer on an individual's QoL was included:

5.1.4.1.3 The Patient Generated Index (PGI) (page 412)

Individualised QoL was assessed with The Patient Generated Index (PGI) (Ruta et al., 1994), which is a well used and validated questionnaire that has been used with a wide range of patient groups, such as cancer patients(Camilleri-Brennan, Ruta, & Steele, 2002), rheumatological conditions (Ruta *et al.*, 1994; Tully & Cantrill, 2000), ankylosing spondylitis (Haywood, Garratt, Dziedzic, & Dawes, 2003), in disabled populations (Lintern, Beaumont, Kenealy, & Murrell, 2001; MacDuff & Russell, 1998) and individuals with lower limb amputations (Callaghan & Condie, 2003). The measure has acceptable reliability and validity (Ruta *et al.*, 1994), however, its use with certain populations and clinical trials remains controversial (Patel et al., 2003; Tully et al., 2000).

The PGI is a three-stage self-completed measure. The first stage involves identifying a maximum of five areas of life that are affected by the disease. Two other completed boxes are provided in addition, consisting of 'areas affected by other health problems' and 'all other non-health areas of life'. In the second stage, the respondent provides a rating of the degree to which reality meets expectations in each area listed (on a scale of 0 to 10, 0 representing the area as being the worst imaginable and 10 being exactly as wanted). In the third stage, the respondent is asked to imagine that any of these areas of life could be improved. The respondent is given fourteen imaginary points to be spent on whatever areas are deemed to be the most important at that time. Finally an overall PGI score of between 0 and 10 is calculated, with higher scores representing better individualised QoL.

The version of the PGI used in this thesis is also disease specific, meaning that respondents were prompted to think about areas of their life affected by their cancer and treatment. In addition, the trigger list of suggested areas (provided as a precursor to stage 1) was modified from the original to include examples of difficulties commonly mentioned by head and neck cancer patients in the qualitative interviews. For example, loss of independence, other people's reactions, lack of confidence, difficulty eating, etc were added as areas that other patients had mentioned. The trigger list is intended to help people think about areas of life that may have been affected by their condition.

The PGI can be self-completed, however, patients were advised that the researcher was able to provide assistance and explain how to fill it in correctly if required.

For follow-up assessment, two main methods are commonly used. One is the 'open' format, whereby patients are simply asked to complete the questionnaire, as in the first instance, where any areas affected can be added at stage 1. The alternative 'closed' method is where patients are

supplied with the areas they suggested in this section of the questionnaire on initial assessment, and asked to score how they currently feel they are performing in that area and how they would currently allocate points. This allows for the measurement of change over time within the same areas, which would be important for evaluating an intervention study. In this thesis, the former 'open' method has been adopted, as it is more important to investigate how people change their priorities over time and explore whether there are any common life priorities that people have at certain periods that can be associated with adaptive processes rather than the 'closed' method.

Scoring procedure

The following equation is used to derive the overall PGI score:

PGI score = (score 1 x (spend 1/14)) + (score 2 x (spend 2/14) + (score 3 x (spend 3/14)) + (score 4 x (spend 4/14) + (score 5x (spend 5/14)) + (score 6 x (spend 6/14) + (score 7 x (spend 7/14)

Missing data

A PGI response was considered incomplete and not scored if any of the three stages was not completed, or if the allocation of points in stage three did not add up to 14, as this made it impossible to generate a final score.

In the cross-sectional study of post-treatment adaptation, a measurement instrument designed to elicit the cognitive component of Subjective Well-being was selected as the main outcome measure. After assessing in detail patient's perceptions about their illness and treatment and including many different measures of QoL in the main prospective study, in order to reveal change over time, wider issues of adaptation relating to satisfaction with life in general, were assessed.

5.1.4.1.4 The Satisfaction With Life Scale (SWLS) (page 440)

The Satisfaction with Life Scale (SWLS) is a well-validated measure that assesses the cognitive component of subjective well-being (Appendix XI). The SWLS allows respondents to weigh domains of their lives in terms of their own values (Diener, Emmons, Larsen, & Griffin, 1985; Pavot & Diener, 1993). It consists of five statements measured on a seven-point Likert scale (completely agree to completely disagree). Cronbach's alpha (0.80 to 0.89) and test-retest reliability (0.54 to 0.83) have been reported to be within an acceptable range. Factor analysis have indicated that all five items load onto one general factor of well-being (Pavot, Diener, Colvin, & Sandvik, 1991). A total life satisfaction score is obtained by summing the five items (range 5-35).

One term included in item 4 of the questionnaire that was considered an 'Americanism' was changed (from 'gotten' to 'gained').

5.1.4.2 Measures for predictive/ explanatory factors

Some of the psychological measures applied in this research have previously been used with HNC samples, for example the Hospital Anxiety and Depression Scale, the Life Orientation Test and the COPE inventory, however some have never been used with HNC patients. Specific measures were chosen for this very reason, i.e. in order to be able to compare outcomes across the literature, in addition to providing novel data from a psychological perspective.

Illness representations were assessed using the Revised Illness Perception Questionnaire (IPQ-R) (Moss-Morris *et al.*, 2002) and the Brief Illness Perception Questionnaire (BIPQ) (Broadbent et al., 2005).

5.1.4.2.1 The Revised Illness Perception Questionnaire (IPQ-R) (pages 403-405)

The IPQ-R comprises eight scales providing a quantitative assessment of nine components of illness representations, as described in Leventhal's self-regulatory model of illness (Leventhal et al., 1980; Leventhal et al., 1984; Leventhal et al., 1997). The psychometric properties of the original IPQ measure (Weinman et al., 1996), assessing *five* cognitive components of illness representation, have been well established in the literature (see chapter 3). The five component IPQ assesses a patient's illness *identity* (symptoms attributed to the illness), *cause* (personal perceptions of the likely cause of the illness), *cure/control* (beliefs about the likelihood of cure or control of the illness), *time-line* (beliefs about the duration of the illness) and *consequences* (the personal repercussions of having the illness on the patient). Quantitative support for the structural relations between these constructs and a wide range of psychological outcomes such as coping (Helder et al., 2002; Rutter et al., 2002); mood (Vaughan et al., 2003); functional adaptation (Han et al., 2005) and adherence to medical regimens (Llewellyn, Miners, Lee, Harrington, & Weinman, 2003) have also been documented. After extensive retesting, the new version of the IPQ, the IPQ-R, also incorporates another important component of Leventhal's model, *emotional representations* that were previously overlooked. The addition of representations of *cyclical timeline* beliefs (perceptions of the unpredictability of the symptoms or illness), perceptions of *treatment control* (beliefs about the ability of treatment to control the illness), *illness coherence* (the patients understanding of the illness through their own representations) and *emotional representations* (the feelings produced by the illness), assesses the dualistic nature of Leventhal's model (i.e. the cognitive components and the emotional components) that result in response to the health threat. The psychometric properties of the nine component measure has been evaluated with many different patient samples, such as, patients with asthma, diabetes, chronic and acute pain, multiple sclerosis and HIV (Moss-Morris *et al.*, 2002).

A short (18-item) version of the IPQ-R was used in the present study in order to reduce responder burden (Appendix VII), in addition, treatment control beliefs were not included as these were assessed by items of the Beliefs about Medicines Questionnaire (BMQ).

Scoring

The identity scale in the current study is comprised of fifteen core symptom items that the patient is asked to rate in two ways. Firstly, the patients are asked to rate whether or not the symptom has been experienced since the onset of the illness (yes/no format). Secondly, they are asked whether each symptom experienced is specifically related to their illness (yes/no format). The sum of yes rated items from the second step results in the illness identity score.

The symptom list consisted of items from the IPQ-R and additional items commonly known to be associated with HNC e.g. difficulties eating or difficulties speaking. It is recommended that the core list of symptoms can be added to in order to make the scale more specific.

The subscales of acute/chronic timeline, cyclical timeline, consequences, illness coherence, personal control and emotional representations each consist of three items and are rated on a five point scale (1=strongly agree to 5= strongly disagree). Scores can range from 3 to 15 with higher scores indicating a stronger belief. Some of the items require reverse scoring.

The *cause* scale was assessed by asking patient's to list in rank order the three most important factors believed to have caused the illness. This scale is not scored but assessed qualitatively for content. No prompt box was supplied.

5.1.4.2.2 The Brief Illness Perception Questionnaire (BIPQ) (pages 442-443)

The BIPQ is a new theoretically derived 9-item scale designed to assess the cognitive and emotional representations of illness based on the IPQ-R (Broadbent et al., 2005). All of the

dimensions except the causal dimension (not included in this study) are assessed using single items on 0 to 10 response scales. Six of the items assess cognitive illness representations, of; identity, consequences, time-line, coherence, personal control and treatment control. The psychometric properties of this new measure have been assessed using six illness groups of: myocardial infarction, renal disease, type 2 diabetes, asthma, minor illnesses (allergies, colds, headaches) and a sample undergoing stress-exercise testing prior to diagnosis. The measure has demonstrated good retest-reliability, and good concurrent, predictive and discriminant validity within these patient groups.

The BIPQ was chosen for use in follow-up assessments, in order to reduce responder burden. The qualitative causal items were not included in this study as they had been assessed previously (Appendix XII).

5.1.4.2.3 The Beliefs about Medicine Questionnaire (BMQ) modified (page 405)

Patient's representations regarding the treatment for cancer were measured using a modified version of the 'Specific' subscale of the Beliefs about Medicines Questionnaire (BMQ) (Horne, Weinman, & Hankins, 1999). The Specific scale assesses two further subscales of treatment *Necessity* and treatment *Concerns*. Treatment Necessity contains five items pertaining to beliefs about the need for and efficacy of treatment (in this instance, surgery, radiotherapy and /or chemotherapy), whereas, the five items of the treatment Concerns subscale assesses beliefs about the possible harmful effects of treatment. The following original item from the Concerns subscale was not included in this thesis, 'I sometimes worry about becoming too dependent on my medicines', as it was not considered relevant to the types of treatment modalities commonly used with head and neck cancer patients. Cronbach's alpha based on the four remaining items of the scale proved acceptable (see Chapter 8)[6].

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[6] Only two items from the Necessity subscale and two items from the Concerns subscale were administered in the follow-up assessments (at time 2 and time 3). This was due to issues of relevance after

Whilst, the IPQ and BMQ are generic instruments, they are intended to be modified for use within specific illness groups. In this instance, the term 'medication' was replaced with the word 'treatment' (which remained generic in order to apply to all different treatments).

Scoring

Responses to each of the statements are scored on a five-point Likert scale from strongly disagree to strongly agree. Scores for each scale range between 4 and 20 for the treatment Concerns subscale, and 5 and 25 for the treatment Necessity subscale. Higher scores on each subscale indicate increasing concerns over the harmful effects of treatment but stronger beliefs about the necessity of treatment.

The psychometric properties of the BMQ have not previously been tested in HNC patients, however, the internal consistency, reliability and validity of the scales have been reported as acceptable with many acute and chronic illness groups (Horne et al., 1999; Horne et al., 2002; Llewellyn et al., 2003).

5.1.4.2.4 The Hospital Anxiety and Depression Scale (HADS) (pages 415-416)

Depression and anxiety was assessed with the Hospital Anxiety and Depression Scale (HADS) (Zigmond et al., 1983). The HADS is a well known and validated 14-item scale developed to provide a brief measure of both anxiety (seven items) and depression (seven items) in out-patient settings. It was chosen to measure state and not trait anxiety and depression, without the contamination of scores by physical symptoms. In addition, this relatively brief measure reduces responder burden when used with other measures. The two subscales have been reported in the literature as having Cronbach's alphas of approximately 0.90 for both anxiety and depression (Moorey et al., 1991).

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treatment had been discontinued. These items can be found in Appendix XIII. Scores can range from 2-10. The internal reliability of the two subscales consisting of two-items each can be found in Chapter 8.

Scoring

Each item is scored from 0 to 3, therefore the total scores range from 0 to 21 for each of the two subscales (some of the items require reverse coding). High scores indicate greater levels of anxiety or depression. Zigmond and Snaith (1983) suggest that scores from 8 to 10 on each scale indicate a possible clinical disorder and scores from 11 to 21 indicate a probable clinical disorder.

5.1.4.2.5 Life Orientation Test – Revised (LOT-R) (page 419)

Dispositional optimism (habitual style of anticipating favourable outcomes) in patients was assessed using the revised version of the Life Orientation Test (LOT-R) (Scheier & Carver, 1987) which is a brief version. The LOT was developed to assess individual differences in generalised trait optimism versus pessimism and originally consisted of eight items. Although the LOT has been widely used, it was found to have some problems. Most importantly, its original items did not all focus as explicitly on expectations for the future as theory dictated. In part to remedy this deficiency, a modest revision of the LOT, called the LOT-R has since been developed. The revised version contains six items (plus filler items) and was developed in order to assess generalised optimism amongst many other measures whilst reducing responder burden. The LOT-R has been used in a variety of research studies with cancer patients (Carver, Lehmann, & Antoni, 2003; Penedo et al., 2003) and has been reported in the literature as having a Cronbach's alpha level of approximately 0.75 (Carver et al., 2003).

Scoring

Each of the six items is rated on a 5-point scale of agreement from 1=' disagree a lot' to 5= 'I agree a lot'. These are summed to provide a single score. High scores indicate high optimism. However, it has been argued that high scores on the LOT may actually reflect low neuroticism (Smith, Pope, Rhodewalt, & Poulton, 1989).

The four filler items that were designed to disguise the purpose of the test, were not included, in order to reduce the overall number of items.

5.1.4.2.6 Brief COPE (pages 417-418)

Coping style in response to the recent cancer diagnosis was assessed using the Brief COPE inventory (Carver, 1997). This is a brief, 28-item inventory, consisting of 14 scales. The Brief COPE is an abbreviated and slightly adapted version of the full version COPE inventory (Carver et al., 1989), developed from theory and previous research which demonstrated the role of the subscales in facilitating or impeding adaptive coping in different contexts. The shorter set of items was developed due to responder burden not only with the length of the questionnaire but with redundancy of items within the full version. The coping scales of the Brief COPE are as follows: Self-distraction, active coping, denial, substance use, use of emotional support, use of instrumental support, behavioural disengagement, venting, positive reframing, planning, humour, acceptance, religion and self-blame. The Brief COPE has been used by the authors in research with breast cancer patients and community samples recovering from natural disasters.

Internal consistency reliability coefficients (Cronbach's alpha) have been found to vary from 0.40 to 0.90 (Carver, 1997; Vosvick et al., 2003). The variability in the reliability coefficient across studies may indicate that this scale is more reliable when measuring acute stressors than when measuring chronic, ongoing stressors such as patients living with a chronic illness. Clearly, more studies that use this scale across different types of life stressors, both acute and chronic, are needed to fully understand this observed difference.

Scoring

Scales are computed by summing the scores from the appropriate 2 items, and since the scores for each item range from 1 (I haven't been doing this at all) to 4 (I've been doing this a lot), the scores range from 2 to 8.

Missing data

In general, if there were only 2 items in a subscale, missing data could not be replaced and the subscale was not computed. If a scale consisted of at least 5 items, one or two missing values were calculated from the mean value for the scores that existed.

Novel measures to assess patient satisfaction with information and expectations

Where no appropriate validated measures could be found in the literature, novel measures were devised and subsequently validated.

5.1.4.2.7 Satisfaction with Cancer Information Profile (SCIP) (pages 413-414)

No measures explicitly to assess satisfaction with information for use with HNC patients could be found. Informational needs and satisfaction with information was therefore assessed with a novel questionnaire. The items were derived in part from the Satisfaction with Information about Medicines Scale (SIMS) (Horne, Hankins, & Jenkins, 2001)and common themes arising from the qualitative study (chapter 4). See Methods Part 2 for development and psychometric testing of this measure.

The questionnaire consists of 21 items and two open-ended questions giving two sub-scale scores.

Subscale one: Satisfaction with the amount and content of information

A rating of the satisfaction with the amount and content of information is achieved by scoring items 1 to 14. Participants responding to items with either ' about right' or 'none needed' are given a score of 1. If the participant is dissatisfied with the amount of information of information received i.e. responding with 'too little' or 'too much', are scored 0. Scores range from 0 to 14 with high scores indicating a high degree of overall satisfaction with the amount and content of information received.

Subscale two: Satisfaction with the form and timing of the information received

A rating of the level of satisfaction with the form and timing of the information received is achieved from responses to items 15-21. Each item is rated on a five-item response scale from 'very satisfied'=5 to 'very dissatisfied'=1 with a neutral category of 'neither'=3 in the middle. The responses are summed to give the overall satisfaction score with the form and timing of information. Scores range from 7 to 35 with higher scores indicating higher levels of satisfaction.

Measures of internal consistency for each of the subscales were high and within the acceptable level. Inter-correlations between the subscales proved good demonstrating that the two components of the SCIP were measuring related constructs of 'satisfaction'. Two types of criterion- orientated validity were demonstrated: concurrent validity and predictive validity. The measure was also shown to be easily completed by patients and responsive to change.

5.1.4.2.8 Patient Expectations (page 447)

Expectations regarding treatment and recovery are assessed using three novel questions derived from the qualitative study asking to what degree expectations have been met by the patient's experience to date (Appendix XIV). Specific questions and their method of scoring are shown overleaf:

Expectation 1. To what degree have your expectations regarding the outcome of treatment been met? (i.e. cosmetic and/or physical effects of treatment)

Expectation 2. At present, to what degree have your expectations regarding the extent of recovery currently been met?

Expectations 1 and 2 have four category responses in order to gauge whether expectations had been surpassed or unfulfilled: 'better than expected', 'about the same as expected', 'worse than expected' and 'no expectations at all'. Each question is analysed separately according to the specific research question.

Scoring of items 1 and 2

Items 1 and 2 are scored to provide a dichotomous measure of the extent of fulfilment. Responses of 'same as expected' and 'better than expected' are scored 1 indicating expectations fulfilled. Responses of 'worse than expected' are scored 0 to indicate that expectations were not fulfilled. A response of 'no expectations at all' are not included in analysis but can be used for descriptive purposes.

Expectation 3. To what extent have your expectations regarding the whole treatment and recovery period to date been fulfilled by your experiences?

Item 3 has a different response frame to items 1 and 2 above as it does not allow the individual to answer that they had no expectations. The four response categories are scored as an ordinal measure as follows: 'not at all as I expected'=0, 'somewhat as I expected'=1, 'mainly as I expected'=2 and 'completely as I expected'=3. This measure provides a score of the degree of fulfilment of more general expectations after treatment. For all three items, higher scores indicate that expectations have been met more fully.

5.1.4.2.9 Additional data

Socio-demographical information was collected by questionnaire. Where data were missing from the questionnaire, medical notes were hand-searched and information abstracted (where available).

Clinical and treatment related information was collected through information returned with the questionnaire. Where data were missing, medical notes were hand-searched and information abstracted (where available).

5.1.5 Statistical analysis - General Methodology

5.1.5.1 Treatment of data prior to analysis

Outliers shown to be extreme with stem and leaf plots were removed prior to analysis after checking to ensure they were not typing errors.

Assumptions for parametric data were explored by plotting the frequency distribution of scores (histograms) and summary statistics for the distribution of values (kurtosis and skewness). The values of kurtosis and skewness should be 0 in a normal distribution, however, the actual scores provided by SPSS are uninformative. The scores were standardised using the following formulae (Field, 2000):

$$Z_{skewness} = \frac{skewness - 0}{SE_{skewness}}$$

$$Z_{kurtosis} = SQRT \left(\frac{Kurtosis - 0}{SE_{kurtosis}} \right)$$

The values of skewness, kurtosis and their respective standard errors (SE) are calculated by SPSS. The z scores can then be compared against values that could be expected from chance. A value above 1.96 is considered significantly different from chance to be problematic. In small

samples this criterion should be increased to 2.58 (Field, 2000). However, ± 3.2 can be considered a reasonable cut-off point. Kolmogorov-Smirnov (K-S) tests were also run as a final check of whether distributions were normal. Many series of data are characterized by greater oscillations when series values are bigger in magnitude than when they are smaller (a form of heteroscedasticity). Therefore, variables violating parametric assumptions (i.e. a significant K-S test) and shown to be negatively skewed, were subject to attempts at logarithmic transformation, either to base e (the LN function) or base 10 (the LG10 function), in order to make variation constant across levels of the series (base e transformation requires that all values be positive.) Variables violating parametric assumptions (i.e. K-S test was significant) and shown to be positively skewed, were subject to attempts at square root (SQRT) transformation. Variables still non-normally distributed were analysed using non-parametric tests.

5.1.5.2 Statistical analysis

Data were analysed using the Statistical Package for the Social Sciences versions 11 and 12 (SPSS for Windows, SPSS Inc., Chicago, IL, U.S.A). A variety of parametric and non-parametric techniques were used throughout the thesis. Details of specific statistical procedures can be found in chapters 6, 7, 8 and 9.

Data obtained from the majority of these questionnaire measures were considered to be ordinal, which is usually thought to preclude parametric statistical techniques such as parametric correlations, multiple regression etc. However, in regard to the use of multiple regression, (which assumes interval data), with ordinal Likert scale items, Jaccard and Wan (1996) summarize in a review of the literature on this topic, "for many statistical tests, rather severe departures (from intervalness) do not seem to affect Type I and Type II errors dramatically" (Jaccard & Wan, 1996). Similarly, other researchers have demonstrated the robustness of correlation and other parametric coefficients with respect to ordinal distortion (Binder, 1984; Kim, 1975; Labovitz, 1970; Zumbo & Zimmerman, 1993). Use of ordinal

variables such as 5-point Likert scales with interval techniques is the norm in contemporary social science. Use of scales with fewer values not only violates normality assumptions but also runs a heightened risk of confounding.[7]

5.1.5.2.1 Differences between responders and non-responders

Independent t-tests (for continuous parametric data), Chi^2 tests (for categorical data) or Fishers exact tests (where Chi^2 cells were less than 5) and Cramér's V tests (for nominal data) were used as appropriate to investigate any differences in socio-demographic and clinical characteristics between responders and non-responders.

5.1.5.2.2 Relationships between explanatory variables and study outcomes

To test for any relationships between explanatory factors (independent variables) such as socio-demographic, clinical and psychological factors, and study outcomes (HR-QoL, individualised QoL, mood etc), univariate and multivariate tests were conducted. Univariate relationships were assessed using Pearson's correlation coefficients (or Spearman's correlation coefficients if data proved non-parametric). In order to assess the amount of variance explained by each contributing factor, linear regression models were constructed. Where multivariate linear regression models were used, in the majority of cases correlational analyses were conducted first in order to reduce the number of factors entered into final models. All significant correlates identified from univariate analysis were included as explanatory variables. Variables were entered in the regression analyses at $p<0.05$ and removed from the model at $p>0.10$. Generally hierarchical multiple regression models were used in order to test explicit hypotheses. When multicollinearity between variables were present, a stepwise method of entry was chosen in order to reduce this problem (Tabachnik & Fidell, 1996).

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[7] Readers should be aware that there is an opposing viewpoint. Thomas Wilson (1971), for instance, concludes, "the ordinal level of measurement prohibits all but the weakest inferences concerning the fit between data and a theoretical model formulated in terms of interval variables." (Wilson, 1971)

5.1.5.2.3 Tests for linearity, homoscedasticity, multicollinearity, normality and independence of residuals of final regression models

A scatterplot of the models standardised residuals against the standardised predicted values was used to determine the extent of heteroscedasticity and linearity in the data. The plot should be fairly random and evenly dispersed to meet assumptions of homoscedasticity and linearity.

The assumption of normally distributed errors was assessed by plotting a p-p plot of the model's residuals (a straight line should be indicated) and a histogram of standardised residuals (a normal distribution should be demonstrated).

The assumption of independent errors was investigated by examining the Durbin-Watson statistic. This should be 2 or approximately 2 if assumptions are met. Collinearity statistics of tolerance and variance inflation factors (VIF) should be within acceptable ranges (>0.2 and <10 respectively) in order to indicate there is no multicollinearity in the data (Bowerman & O'Connell, 1990).

5.1.5.3 Power calculations

Correlations and multiple linear regression models were constructed to test the main hypotheses. Previous studies (Rutter et al., 2002; Rutter, Durham-Hall, Weinman, & Fidler, 2003; Scharloo et al., 2000) have reported explained variance in outcome (such as QoL or functional status) using illness representations, of approximately 20%, giving an effect size of 0.25. Based on this effect size and the expected number of predictor variables (15), 89 cases would be sufficient to detect an R^2 of 0.20 with 80% power at the 0.05 level of significance.

For 20 variables, 101 cases are deemed sufficient to detect an R^2 of 0.20 with 80% power at the 0.05 level of significance. With R-squared of 0.35, the effect size is very large at 0.54. Therefore the sample size needed would be 49 cases.

5.2 PART 2: Development and preliminary validation of a new measure to assess satisfaction with information amongst head and neck cancer patients: The Satisfaction with Cancer Information Profile (SCIP)

This chapter has been accepted for publication: Llewellyn CD, Horne R, McGurk M, Weinman J. Development and preliminary validation of a new measure to assess satisfaction with information amongst head and neck cancer patients: The Satisfaction with Cancer Information Profile (SCIP). *Head & Neck*

5.2.1 Introduction

Recent United Kingdom Department of Health recommendations (Department of Health, 2000) state that NHS Trusts and cancer services must provide high quality information for cancer patients. Research indicates that cancer patients are being provided with good generic information (Semple & McGowan, 2002), however, recent studies suggest that cancer patients are frequently reporting a mismatch between the level of information that is supplied and their individual informational requirements (Ziegler, Newell, Stafford, & Lewin, 2004). This is consistent with a report by the National Cancer Alliance (National Cancer Alliance, 2002), who highlighted through discussions with a focus group that although some patients had received written information, this was inadequate for their needs. A study by Edwards (Edwards, 1998), also underlined the lack of satisfaction regarding information giving. It was suggested that head and neck cancer patients wanted to have more information about the impact of their treatment and about different treatment options rather than details of the operation. In addition, Mesters

and colleagues, (Mesters, van den Borne, De Boer, & Pruyn, 2001) found that more supportive information about access to help and solutions was required.

The following questionnaire was developed as a result of findings from both the literature and the qualitative pilot research (Chapter 4). It was apparent from the pilot study that patients received (or retained) different amounts of information, and there were many aspects of the treatment and recovery that many patients were not prepared for. Moreover, there were differences in the amount of information that patients required and some patients reported that they did not feel able to ask particular questions during the consultation, especially those related to non-medical factors, for example, QoL related issues after treatment. It also became apparent from talking to patients and staff in different treating departments that the amount and type of information given to HNC patients were diverse. It has previously been reported that unmet informational needs and low satisfaction with information provided is related to unfavourable patient outcomes, such as, lower HR-QoL and higher levels of depression and anxiety (Edwards, 1998; Mesters et al., 2001), therefore, it is valuable to address these issues prior to treatment.

A search of the literature found no questionnaires suitable for assessing the extent to which cancer patients (particularly HNC patients), undergoing a variety of treatment regimens, receive *enough* information about the amount and content, and the format and timing of the information with a wide range of aspects of the illness, treatment, recovery and long-term consequences of the disease. Although other measures of informational need in cancer exist (Degner et al., 1997; Graydon et al., 1997; Mesters et al., 2001), they fail to capture the patient's perspective in terms of whether they have received *too much* or *too little* information and thus how satisfied they are with the level of information supplied. This approach however, has been applied to the assessment of satisfaction with information relating to medication which resulted in a published and validated measure The Satisfaction with Information about Medicines Scale

(SIMS) (Horne et al., 2001) which assesses the extent to which individuals perceive that the information given to them about their medication has met their needs. The SIMS was developed in response to published recommendations of the Association of the British Pharmaceutical Industry for the type of information patients require in order to facilitate the safe self-management of medication (Association of the British Pharmaceutical Industry, 1988).

Based on the SIMS framework and in response to the outstanding issues highlighted by The National Cancer Alliance and other recent studies, a novel measure was developed to assess the extent to which head and neck cancer patients are satisfied with information received about their treatment. The current objectives of this preliminary study were to describe the development of a new measure and to establish its psychometric properties.

5.2.2 Methodology

5.2.2.1 Questionnaire item development

The Satisfaction with Cancer Information Profile (SCIP) was developed as a result of qualitative interviews with a convenience sample of fifteen post-treatment head and neck cancer patients and a search of the literature for existing measures. Four of the items were adapted from a validated questionnaire, the Satisfaction with Information about Medicines Scale (SIMS) (Horne et al., 2001) with the author's permission (items included: whether the treatment has any unwanted side-effects; what the risks of you experiencing side effects are; what you should do if you experience unwanted side-effects; whether your treatment interferes with other medicines you may be taking). Additional items regarding specific aspects of the treatment and recovery were derived from the qualitative pilot interviews. For example, some participants mentioned that alternative types of treatment had not been discussed thoroughly and some had been unsure of what the risks of side-effects had been. On a more practical level, participants had also not been given any information regarding whom to ask about possible financial assistance and the availability of support groups for patients with head and neck

cancer. The response framework for the first subscale of the new measure (extent of satisfaction with the amount and content of information) was also based on the SIMS framework, whereby, patients are asked to indicate whether they have received *enough* information.

Key issues of a general nature also emerged from the qualitative interviews. For example, participants indicated that one of the main issues had been around the amount of information and the detail. This was demonstrated on a continuum of not having enough information to having too much information (see chapter 4). Related to this was the issue of timing. The majority of newly diagnosed patients felt that too much detailed information early on was overwhelming, which has clear implications for the provision of written information, which can then be taken home to read at an appropriate time. Similarly, issues of relevance and understanding of the information were key concerns that emerged from the interviews and are consistent with other findings (Newell, Ziegler, Stafford, & Lewin, 2004). Post-treatment patients were selected for interview, as opposed to pre-treatment patients, in order to elicit whether there had been any aspects of information that had been missing after actually experiencing treatment and the beginning of the recovery process. It is often in retrospect that patients wish they had been told certain aspects. Therefore, key issues of: the usefulness of the information to themselves and their family; the medium of the information i.e. the amount of written and verbal information; the appropriateness of the timing of information; the detail and the subsequent level of understanding, formed the basis for items in the 'Satisfaction with the type and timing of information' subscale. As these items were measuring overall levels of satisfaction with each aspect, a five-point likert scale was chosen for the response framework.

Two open-ended questions were also added to allow participants to add their thoughts on any aspects of the information giving process they thought important for us to know. This section

is also pragmatic, as it allows the clinician to be aware of any aspects that the patient is unsure about, that they may not wish to raise verbally during the consultation.

The questionnaire was prefaced with the statement, 'we would like to ask you about the information you have received about your treatment for cancer. Firstly, please answer whether you have received any information about the following aspects of your treatment and secondly, rate the amount you have received (if applicable). If you are having or have had more than one type of treatment please give your overall feeling about the information you have received.

5.2.2.2 Participants

The analysis is based on data supplied from 82 participants recruited into the main prospective study from hospitals in the south east of England (see chapter 5: Part 1 for more details). Data were collected at two time points, prior to treatment (baseline) and one month after the end of treatment. Follow-up data were supplied by 68 participants (83% of the original cohort). More details regarding these samples of patients can be found in chapters 6 and 8.

5.2.2.3 Item analysis

The original questionnaire containing 27 items can be found in Appendix VII. Prior to testing the reliability and validity of the final questionnaire, item analysis was conducted on the original items. In order to check that each item was measuring a wide range of responses, the standard deviations of responses to each of the items were examined. Items were rejected if their standard deviations were lower than 0.4. This was to ensure that the distribution of scores for each item was relatively widely dispersed. Four items (items 1 to 4, see Appendix XV) with standard deviations of lower than 0.4 were deleted from the final questionnaire. In addition, in order to assess whether all the statements were measuring similar constructs, the item-total correlations were examined. Any item with a low item-total correlation (i.e. <0.3 or negative)

was removed. No additional items were removed (see Appendix XVI). Table 5.4 displays the items retained and items deleted from the final questionnaire.

5.2.2.4 Scoring of the SCIP

The final questionnaire consists of two subscales and a free-response section, which require different responses.

- **Subscale one: Satisfaction with the amount and content of information**

The 'satisfaction with the amount and content of information' subscale consists of items relating to the quantity and content of the information. Participants are asked to rate the amount of information they received on items 1 to 14 using the following response scale: 'too much', 'about right', 'too little' and 'none wanted' (see Appendix XVI). Satisfied participants responding to items with either ' about right' or 'none needed' are given a score of 1. If the participant is dissatisfied with the amount of information received i.e. responding with 'too little' or 'too much', items are scored 0. A subscale score is obtained by summing the scores for each item. Total scores range from 0 to 14 with high scores indicating a high degree of satisfaction with the amount and content of information received. This response format is the same as the previously published and validated SIMS measurement tool (Horne et al., 2001). In addition, an individualised information profile can be obtained for each patient by examining the ratings on each specific item. Any deficiencies in information can then be given to the patient prior to treatment.

Missing data

If more than 50% of the items are not completed a summary score cannot be calculated.

Where at least seven of the fourteen items are completed, mean values are estimated for the missing items, and a subscale score calculated.

- **Subscale two: Satisfaction with the form and timing of the information received**

A rating of the level of satisfaction with the form and timing of the information received is achieved from subscale two. This section contains seven items (items 15 to 21), each rated on a five-item response scale from 'very satisfied'=5 to 'very dissatisfied'=1 with a neutral category of 'neither'=3 in the middle. Examples of the items are: 'the amount of written information supplied', 'the amount of verbal information supplied', and ' how understandable the information was to you'. The responses are summed to give a satisfaction score with the type and timing of information. Scores range from 7 to 35 with higher scores indicating higher levels of satisfaction.

Missing data

Where at least four of the seven items are completed, mean values are estimated for the missing items and a final score calculated.

The last section consists of two open-ended questions 'is there any further information you wish you had received?' and 'is there anything else you would like to add regarding the information you received?' Participants can then add any recommendations or concerns they have in their own words. The responses can then be content analysed for research purposes or used on an individual basis.

Table 5.4: Items deleted and items retained in final questionnaire

	Item retained	Item deleted
Subscale: Satisfaction with the amount and content of information	Whether the treatment has any unwanted side-effects	What your diagnosis means to you
	What the risks of you experiencing side effects are	The types of treatment suitable for you
	What the risks of you experiencing complications are	The expected benefit of treatment
	What you should do if you experience unwanted side-effects	What procedures your treatment will involve
	Whether your treatment interferes with other medicines you may be taking	-
	How you may expect to feel immediately after treatment	-
	The effects of treatment on your ability to work	-
	Who to ask/where to go for possible financial support	-
	Whether you may need further treatment in the future	-
	The effect of treatment on your appearance	-
	The long term impact of treatment on functioning (daily activities)	-
	How long you expect recovery to take	-
	How your treatment may impact on your quality of life over the next year	-
	Patient support groups for you and your partner	-
Subscale: Satisfaction with the form and timing of information	The usefulness of the information to you	-
	The usefulness of the information to your partner/family	-
	The amount of written information supplied	-
	The amount of verbal information supplied	-
	The timing at which you received information	-
	The detail of the information given to you	-
	How understandable the information was to you	-

5.2.2.5 Psychometric validation of the final questionnaire

The new measure underwent psychometric validation in order to comment on the reliability, validity, sensitivity to change and ease of completion of the instrument, through a series of tests described below. One outlier was removed from the pre-treatment subscale 2: the form and timing of information. Kolmorogov-Smirnov tests demonstrated that the majority of the data were non-normally distributed ($p<0.05$) and, therefore, non-parametric tests were conducted throughout. The following additional measures were used in the validation process of the SCIP:

- The Revised Illness Perception Questionnaire (IPQ-R)
- The Brief Illness Perception Questionnaire (BIPQ)
- The Beliefs about Medicine Questionnaire (BMQ)
- The Hospital Anxiety and Depression Scale (HADS)
- The Life Orientation Test - Revised (LOT-R)
- The European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 (version 3)

The measures used and rationale for their use can be found under each test heading.

5.2.2.5.1 Reliability

5.2.2.5.1.1 Internal consistency

The internal consistency of a scale estimates the extent to which items are measuring the same construct. Cronbach's alpha was calculated for each of the subscales and the overall satisfaction score. Scores range from 0 to 1, whereby 0 indicates no internal consistency (items are unrelated) and 1 indicates a high level of consistency. An acceptable level for Cronbach's alpha are scores >0.8.

5.2.2.5.1.2 Subscale inter-correlations

Spearman correlation coefficients between the two subscales were conducted to assess the degree to which the two types of satisfaction (amount & content versus form & timing) were correlated. This was to ensure that the two subscales were assessing related but distinct constructs of 'satisfaction'.

5.2.2.5.2 Validity

Validity refers to the degree to which an instrument accurately reflects or assesses the specific concept that the researcher is attempting to operationalize. While reliability is concerned with the consistency of the actual measuring instrument or procedure, validity is concerned with the instrument's success at measuring what the researchers set out to measure.

5.2.2.5.2.1 Criterion related validity

Criterion related validity, also referred to as instrumental validity, is used to demonstrate the accuracy of a measure or procedure by comparing it with another measure, which has been demonstrated to be valid (referred to as the 'gold standard'). This is often not possible if gold standard tools are not available, therefore, criterion validity is judged on the basis of relationships between the measure and proxy measures. Hypotheses can then be tested based on the relationships between the constructs. Criterion validity is usually divided into two types: concurrent (convergent) and predictive validity.

5.2.2.5.2.1.1 Concurrent (convergent) validity

Concurrent validity was assessed using Spearman correlation coefficients to assess the relationships between satisfaction with information and pre-treatment illness beliefs. It was hypothesised that patients' requirements for information and thus their satisfaction with the information received would be dependent upon key beliefs about the personal controllability of the illness (i.e. what they could do to get better), how well they understood their illness and

how ill they currently felt (i.e. how many symptoms they were experiencing). Thus, patients with more symptoms (a stronger illness identity), weaker perceptions about the personal controllability of the illness and a low sense of illness coherence would require high levels of information and, therefore, may be less satisfied with the information received.

Scores on IPQ-R subscales of illness identity, personal control and coherence were used to test these hypotheses.

5.2.2.5.2.1.2 Predictive validity

The ability of the instrument to predict levels of future variables, in the expected directions, was assessed by testing hypotheses regarding the relationships between pre-treatment satisfaction with information and key outcome variables and beliefs one month after treatment. It was hypothesised that low satisfaction with information pre-treatment (unmet needs for information) could affect psychological well-being after treatment and thus the SCIP would be correlated with high scores on indicators of emotional distress and outcomes such as QoL. Cross-lag Spearman correlation coefficients were calculated to test the following research questions and hypotheses:

1) Does level of satisfaction with information prior to treatment predict a number of key outcomes related to psychological well-being after treatment? It was hypothesised that low levels of satisfaction with information prior to treatment would be related to low levels of quality of life and high levels of depression after treatment.

The level of information received prior to treatment may be an important influential factor in the formation of patients' post-treatment beliefs about their illness and treatment. Patients' who were less satisfied with the level of information they received may not be fully aware of the high necessity of treatment for their current health status (given that the experience of side-

effects one month after treatment may still be severe). Similarly, patients' may be less aware of the treatment's ability to control the disease due to overriding perceptions of the high negative consequences of having the illness and treatment.

Therefore the following research question was investigated:

2) Does level of satisfaction with information prior to treatment predict key illness and treatment beliefs after treatment? It was further hypothesised that low levels of satisfaction with information prior to treatment would be related to: weaker beliefs about both the necessity of treatment and the controllability of the illness through treatment, a higher number of symptoms and perceptions of high negative consequences of the disease, after treatment.

The EORTC QLQ-C30 overall QoL score, the HADS depression subscale, BIPQ subscales of treatment control, consequences and illness identity, and the necessity subscale of the BMQ-specific were used to test these hypotheses.

5.2.2.5.2.2 Discriminant validity

Discriminant validity is a type of construct validity and is used to establish whether scores on the new measure are distinguishable from a non-related construct. This was tested by calculating Spearman correlation coefficients between pre-treatment satisfaction with information and a measure of personality (using the LOT-R). This was to ensure that responses on the satisfaction questionnaire could not be explained by differences in personality.

5.2.2.5.3 Responsiveness to change

The ability of the instrument to detect actual changes over time, particularly after an event of clinical importance, i.e. after treatment in this case, was also assessed. It was hypothesised that informational requirements and therefore aspects of satisfaction with pre-treatment information received would change after treatment as a result of the experience of treatment.

Responsiveness to change was assessed by examining individual items of the questionnaire in addition to subscales. This was in order to be able to detect change in specific areas important to head and neck cancer patients and, secondly, to be able to assess the direction of change that could be masked by analysis at the subscale level.

Binary data (items 1 to 14 of the satisfaction with the amount and content of information subscale) were tested using McNemar tests for repeated measures. Wilcoxen Signed Ranks tests for two-related samples were conducted on ordinal data (items 15 to 21 of the satisfaction with type and timing of information subscale).

5.2.2.5.4 Ease of completion

Ease of completion of the questionnaire by patients was assessed by examining the number of items missing and the response rates of completed questionnaires.

5.2.3 RESULTS

The distribution of pre- and post-treatment scores for each of the subscales and the levels of overall satisfaction are presented as histograms in Appendix XVII. Scores on the Satisfaction with content and amount of information subscale were negatively skewed pre- (mean=9.9; SD=9.9) and post-treatment (mean=10.1; SD=4) with ranges of 14. The median score at both time points was 11. Scores on the Satisfaction with form and content of information were more normally distributed with a pre-treatment range of 13 (mean=28.8; SD=3.5) and post-treatment range of 21 (mean=27.4; SD=5.1).

5.2.3.1 Reliability

5.2.3.1.1 Internal Consistency

Cronbach's alpha coefficients for the two subscales are shown in Table 5.5 Both of the subscales demonstrated good internal consistencies.

Table 5.5: Internal consistency of each subscale derived from the Satisfaction with Cancer Information Profile

	Cronbach's α	Std item α
Satisfaction with the content of information	0.89	0.90
Satisfaction with the form and timing of information	0.87	0.89

r= Spearman correlation coefficients, *p<0.01, **p<0.001

5.2.3.1.2 Subscale inter-correlations

Subscale inter-correlations at baseline and one month post-treatment proved good at r=0.589 (p<0.001) and r=0.658 (p<0.001) respectively. The moderate magnitude of coefficients indicates that the scales tap complementary facets of patient satisfaction but are not redundant.

5.2.3.2 Validity

5.2.3.2.1 Criterion related validity

5.2.3.2.1.1 Concurrent (convergent) validity

To assess concurrent validity, it was hypothesised that key illness beliefs would be associated with satisfaction with information, due to patients' differing needs for information. Analysis demonstrated that patients with a strong illness identity (i.e. reporting more symptoms attributed to HNC), weaker perceptions about the personal controllability of the illness and a weak sense of coherence regarding their illness were less likely to be satisfied with the information received (Table 5.6).

Table 5.6: Correlation coefficients to demonstrate concurrent validity

	Subscale coefficients r (n)	
Variable (pre-treatment) Beliefs about:	**Satisfaction with content & amount of information**	**Satisfaction with form & timing of information**
Symptoms (illness identity)	-0.32** (74)	-
Personal Control	0.29** (75)	0.28** (76)
Illness Coherence	0.30** (76)	-

r= Spearman's correlation coefficients, *p<0.05, **p<0.01

5.2.3.2.1.2 Predictive validity

Predictive validity was assessed by examining whether the level of satisfaction with information prior to treatment predicted a number of key variables after treatment. It was hypothesised that low levels of satisfaction with information prior to treatment would be related to low levels of QoL and high levels of depression after treatment. Correlation coefficients (Table 5.7) demonstrated that levels of satisfaction were associated with QoL and depression scores in the directions hypothesised. Patients who were less satisfied with information pre-treatment were more likely to have lower global QoL scores and high levels of depression post-treatment. It was further hypothesised that low levels of satisfaction with information prior to treatment would be related to weaker beliefs about the necessity of treatment and the controllability of the illness through treatment, more symptoms and stronger beliefs of high consequences of the illness, after treatment. Coefficients demonstrated that patients who were less satisfied with information prior to treatment were more likely to believe that treatment was less necessary and less able to control their illness, suffer more symptoms and feel that the consequences of the illness were high.

Table 5.7: Correlation coefficients to demonstrate predictive validity

Variable (post-treatment)	Subscale coefficients r (n)	
	Satisfaction with content & amount of information	Satisfaction with form & timing of information
Global QoL	0.38** (64)	-
Depression	-0.42** (63)	-
Beliefs about:		
Consequences	-0.45** (65)	-
Treatment Control	0.40** (65)	0.48** (65)
Necessity of treatment	-	0.40** (65)
Symptoms (illness identity)	-0.30* (64)	-

r= Spearman's correlation coefficients, *p<0.05, **p<0.005

5.2.3.2.2 Discriminant validity

Coefficients between the subscales and the LOT-R ranged from r=0.01 to 0.10 (p>0.05).

Therefore, satisfaction with information was not affected by general personality traits such as life orientation (optimism).

5.2.3.3 Responsiveness to change

Satisfaction with form and timing of information (items 19 to 25) were assessed pre- and post-treatment in order to ascertain whether patients' ratings of satisfaction changed after experiencing treatment. It was hypothesised that patients' ratings of satisfaction with information would be significantly worse post-treatment, than ratings made prior to treatment.

Wilcoxen signed ranks tests demonstrated that the following areas were rated significantly lower post-treatment compared with ratings pre-treatment: the usefulness of the information (personally useful) (z=-2.01, p<0.05), the detail of the information (z=-2.99, p<0.005) and understanding of the information (z=-1.97, p<0.05). Satisfaction ratings of the amount of verbal information supplied pre-treatment showed a trend towards being worse although this

was not significant (z=-1.89, p=0.059). The subscale of satisfaction with the form and timing of information was significantly lower post-treatment than pre-treatment (z=-2.13, p<0.05). There were no significant post-treatment changes in items 1 to 14 (p>0.05).

5.2.3.4 Ease of completion

Ease of completion for patients was found to be satisfactory, especially as the new measure was completed as part of a large battery of measures. Table 5.8 shows the percentage of participants completing each item. The response rate of items in subscale one (items 1-14) ranged from 79% to 95%, demonstrating an improvement at follow-up with response rates ranging from 90% to 93%. The acceptability of subscale two was better still, with baseline response rates ranging from 91% to 98% and follow-up response rates ranging from 93% to 97%. The better response rates on the second subscale may have been due to the different response framework.

The acceptability of the SCIP was greater at follow-up, with higher completion rates, possibly due to the natural bias of patients completing the second questionnaire battery. For example, follow-up patients consisted of those who felt well enough to still participate in the study. In addition, the questionnaire would have been familiar on second completion.

Table 5.8: Ease of completion (response rate) of each item of the SCIP

	Subscale 1: Satisfaction with the amount & content of information														Subscale 2: Satisfaction with the form & timing of information						
Items 1-21	Any unwanted side-effects	Risks of side-effects	Risks of complications	What to do if experience side-effects	Interferes with other medication	Feel immediately after	Ability to work	Financial support	Further treatment	Effect on appearance	Long term impact on functioning	How long recovery	Impact on QoL	Patient support groups	Usefulness of info to you	Usefulness of info to partner/family	Amount of written info.	Amount of verbal info.	Timing of info.	Detail of info.	Understanding of info.
Baseline response n (%)	78 (95)	75 (91)	75 (91)	72 (88)	74 (90)	78 (95)	76 (93)	70 (85)	74 (90)	72 (88)	69 (84)	69 (84)	65 (79)	68 (83)	79 (96)	77 (94)	75 (91)	78 (95)	77 (94)	79 (96)	80 (98)
Follow-up response n (%)	63 (93)	63 (93)	62 (91)	63 (93)	62 (91)	61 (90)	62 (91)	61 (90)	60 (91)	61 (90)	63 (93)	62 (91)	63 (93)	62 (91)	66 (97)	63 (93)	66 (97)	66 (97)	65 (96)	66 (97)	66 (97)

5.2.4 CONCLUSIONS AND APPLICATIONS

5.2.4.1 Reliability, validity and acceptability

The final version of the SCIP satisfied psychometric tests and was therefore considered reliable and valid as a measure of satisfaction with information for head and neck cancer patients. Measures of internal consistency for each of the subscales were high and within the acceptable level. Inter-correlations between the subscales proved good demonstrating that the two subscales of the SCIP were measuring related constructs of 'satisfaction with information'.

Two types of criterion- related validity were demonstrated: concurrent validity and predictive validity. As there was no gold-standard tool with which to compare the new measure, a series of hypotheses were tested examining the relationships between the new instrument and other constructs. Concurrent validity proved to be good, with significant correlations between both subscales of satisfaction with information scores and key illness beliefs. As predicted, higher levels of satisfaction were associated with fewer symptoms, stronger beliefs in the ability to personally control their illness and a greater understanding of the illness. Associations were primarily between satisfaction with the content and amount of information and beliefs, although personal control beliefs were associated with the format and the timing of the information provided.

Predictive validity was demonstrated by examining whether satisfaction could predict a number of key outcomes and patient beliefs *after* treatment. As predicted, low levels of satisfaction with the content and amount of information pre-treatment were related to lower levels of global quality of life and higher levels of depression after treatment. In addition, it was demonstrated that patients who were less satisfied with this aspect of information were less likely to believe that their treatment could control their illness, were suffering more symptoms and were more likely to perceive that their illness would have high negative consequences. Scores on the subscale 'satisfaction with the amount and content of the information' proved more predictive

of key outcomes and illness beliefs than satisfaction with the method or timing of the information. Interestingly, satisfaction with the form and timing of the information were predictive of beliefs regarding how necessary the treatment was and similarly, perceptions of how important the treatment was in controlling their disease. One explanation for this could be that patients are getting the information too late and the importance of the treatment has not been fully recognised. Another plausible reason could be that patients are not satisfied with the format of the information, for example, the information may have been imparted verbally and patients then forget the detail of why the treatment is necessary and how it works. This would lead to recollections of the topic covered but not in sufficient detail. Although all the patients in this sample underwent some form of treatment, this finding is noteworthy and it would be valuable to investigate whether beliefs about treatment and control after undergoing primary treatment are predictive of adherence to further treatment, or are influential in the decision making process prior to primary treatment. In the present study we did not have the data to ascertain these relationships.

The ease with which patients completed the SCIP proved satisfactory with fairly low proportions of missing data. This was noteworthy due to the new measure being completed as part of a large battery of measures. Higher completion rates were evidenced at follow-up, possibly due to the bias of patients completing the second questionnaire battery. For example, follow-up patients consisted of those who felt well enough to still participate in the study. In addition, the follow-up questionnaire would have been familiar.

5.2.4.2 Responsiveness to change

Subscale two of the SCIP, 'satisfaction with the form and timing of information', was shown to be responsive to change, with significantly lower satisfaction post-treatment compared to pre-treatment levels. This may have been due to a mismatch between the information supplied pre-treatment and the actual experience of treatment and recovery. It has been suggested that in

order to understand satisfaction, patient's expectations must be taken into account. The relationship between expectations and satisfaction has been demonstrated (Hsieh & Doner Kagle, 1991; Korsch, Gozzi, & Francis, 1968; Williams et al., 1995), however, many studies have failed to find any association between expectations and satisfaction (Sanchez-Menegay, Hudes, & Cummings, 1992), indicating that the relationship is probably more complex than previously thought.

5.2.4.3 Measuring informational needs

Only a few instruments seeking to assess a wide range of informational needs in cancer patients exist and these have tended to focus on the degree to which patients have 'no need' or 'high need' for information on a range of topics (e.g. the patient information need questionnaire (PINQ) by Mesters and colleagues (Mesters et al., 2001). The key difference between the PINQ and other generic informational need measures, and the SCIP is that the informational need instruments only address what patients needs are and not whether these needs have been met. Mesters et al (2001) conclude that future research should focus on the interaction between the need for information and the actual provision in order to predict rehabilitation outcomes. It could be argued that the key is to assess this discrepancy in terms of patient satisfaction.

The SCIP attempts to quickly and easily assess the extent to which individuals perceive that their needs have been met and are satisfied with the amount and content and form and timing of the information provided. Consequently, the measure accounts for the fact that some individuals have higher needs for information than others.

In concordance with our results, it has previously been reported that higher informational needs are related to higher levels of anxiety, depression and psychological complaints in HNC patients (Edwards, 1998; Mesters et al., 2001). These findings could equally be due to patients experiencing unmet needs and not higher needs per se. The few studies published assessing

levels of satisfaction with information, have demonstrated significant associations between satisfaction and outcomes such as HR-QoL (Yu et al., 2001) and rehabilitation (De Boer et al., 1995). During the current validation process it was found that satisfaction with information was also associated with particular patient beliefs before and after treatment. The current tests did not allow for analyses to examine whether the types of beliefs patients hold about their illness and treatment mediate the relationship between informational requirements and outcomes, such as depression and HR-QoL. It could be proposed that information is a major determinant of the meanings assigned to the disease (i.e. the cognitive representation). This may explain why patients who are less satisfied with the information they have received (i.e. unmet informational needs) may hold erroneous beliefs about their illness, for example, about how much personal control they have over their health or the consequences of the disease.

Of greater concern was the finding of a relationship between satisfaction and beliefs regarding the necessity of treatment. Patients who were less satisfied with information were more likely to believe that their treatment was less necessary to their health. There is a wealth of research detailing the consequences of beliefs such as these on levels of adherence to medication and medical regimens (Horne & Weinman, 1999; Llewellyn et al., 2003). This is discussed more fully in chapter 6.

5.2.4.4 Limitations

The SCIP may be limited by indicating higher levels of satisfaction than are actually present, due to weaknesses with the scoring methods employed. Firstly, the first subscale may lack sensitivity due to collapsing four responses into a binary variable of essentially satisfied/not satisfied. This was in order to investigate the main research question. This may have resulted in the disguising of more subtle relationships between varying levels of satisfaction and other variables. Additional ways of scoring these data could be investigated in further research.

Secondly, similar to other coding systems, a percentage of missing values are taken into account by calculating the mean score of the completed items. It is possible that a non-response is an indicator of a negative answer (low satisfaction) as patients may be hesitant to give socially undesirable responses. It has been argued that satisfaction questionnaires lack validity as they may be measuring other concepts such as general attitude towards expressing criticism towards the NHS or treating staff, or loyalty towards the NHS (Baker & Whitfield, 1992; Fitzpatrick, 1993). If non-responses were indicative of low satisfaction, then using a score based on the mean of binary responses would give an over-estimation of satisfaction. Therefore, final scores should be interpreted with a certain amount of caution.

Finally, direct measures of satisfaction have been criticised for tending to yield highly skewed response distributions when used to evaluate specific medical encounters (Ware & Hays, 1988), however, Ware & Hays concluded in their own study comparing direct and indirect measures of satisfaction, that both methods are adequate.

Another potential limitation is that the SCIP predominantly assesses satisfaction with information related to treatment and outcome. Many instruments exist that measure different types of patient satisfaction, and Hall and Dornan's (1988) meta-analysis of satisfaction studies highlight this diversity. The most commonly studied aspects of satisfaction with care were informativeness, overall quality and competence. The least frequently studied were patient outcomes, continuity of care and attention to psycho-social problems (Hall & Dornan, 1988). Although a gold standard measure of patient satisfaction with information does not exist, the SCIP could have been compared against other generic measures of informational need. These other instruments may not directly capture satisfaction, however, the construct of patient satisfaction is probably correlated to some extent with level of information requirement.

An additional weakness is that it was not possible to assess the SCIP's test-retest reliability as we did not have the data to do so. Although weak correlations existed between baseline scores and follow-up scores, it is likely that informational needs and thus satisfaction with information are subject to change over time and with major events such as surgery or radiotherapy. A recommendation would be to assess the test-retest reliability of the SCIP by sending the repeat questionnaire to a sub-sample of patients one week after completing the first and prior to treatment.

This chapter only presents preliminary validation based on one sample of HNC patients. Although the results are encouraging and are based on patients recruited from several hospitals in order to reduce systematic bias, further research is needed to determine whether these psychometric properties remain stable when a different sample of HNC patients, or indeed other cancer patients are assessed, and also to examine the relationships between patient's actual level of knowledge and satisfaction.

5.2.4.5 Applications and further research

Despite the limitations, preliminary analyses demonstrate that the SCIP has acceptable levels of reliability and validity. Therefore, this new instrument has the potential to be applied in both clinical practice, training and research settings.

In terms of uses in training, the SCIP could be used as an assessment tool during the communication skills training of medical students. The SCIP could be given to patients after consultation with the medical student, in order to assess the efficacy of communication skills training on information giving practice.

As many HNC patients, and indeed many other cancer patients, undergo treatment regimens that are managed by multidisciplinary teams, the SCIP could be used to audit patients'

satisfaction with the information they have received as part of their routine care and therefore identify departmental or local targets for improvement.

Providing patients with concise and clear information about their illness and treatment is a fundamental principle of the NHS (Department of Health, 2000) and therefore assessing individuals' satisfaction and need for information would be a major step towards achieving these goals. The SCIP takes into account individual differences in patients' requirements and could aid clinicians in identifying which particular aspects are inadequately addressed during the consultation. Moreover, the open-ended questions at the end of the SCIP allow the patient to identify specific information that they would like to know more about which can then be easily supplied by the healthcare provider (HCP) or referred onto a more specialist team member if appropriate. This section is particularly important if patients have difficulty expressing their uncertainties or questions verbally, consistent with the literature (Van der Molen, 1999).

The SCIP has demonstrated an association between outcomes such as global QoL and depression and patient's cognitive representations of their illness in this patient sample. Consequently, satisfaction with information could be an important target for intervention in order to improve short-term and long-term patient well-being. Targeting unmet informational needs could prove a cost-effective and relatively simple intervention, that could be performed using the SCIP and through dialogue with the relevant HCP. Although Mesters et al., (2001), suggest that informational need is a relatively stable characteristic of the patient, it has been suggested that patients' satisfaction with information could not be expected to be static (Barber, 2001), and thus the SCIP could be administered at multiple time points from diagnosis through to the post-treatment recovery period.

Despite the SCIP's development in response to HNC patients' informational needs, this measure could be applicable to all cancer patients due to its suitability for use with all treatment

modalities. Further research is needed with a wider range of cancer patients in order to revalidate the findings from these preliminary analyses. Moreover, more research is required to improve our understanding of the needs and satisfaction with information in a larger sample of HNC patients in order to improve current information provision.

The findings indicate that patients with lower levels of satisfaction have unmet requirements for information. Although this could be in the direction of 'too much information', it is probable that low levels of satisfaction are indicative of lack of information. Low levels of information may lead to erroneous beliefs about the benefits of treatment and a lack of coherence regarding the illness, which subsequently results in worse outcomes in terms of higher levels of depression and lower levels of QoL. Although this was only demonstrated with uni-variate analysis for validation purposes, further analysis will clarify these and other relationships, for example, the relationship between coping strategy and informational need, in order to inform possible targets for intervention.

CHAPTER 6

HOW SATISFIED ARE HNC PATIENTS WITH THE INFORMATION THEY RECEIVE PRE-TREATMENT? RESULTS FROM THE SATISFACTION WITH CANCER INFORMATION PROFILE (SCIP)

This chapter has been accepted for publication in Oral Oncology.

6.1 INTRODUCTION

Whilst accumulating evidence indicates that lower levels of anxiety and depression are experienced by well-informed individuals (Fallowfield, Baum, & Maguire, 1986), the majority of the literature tends to focus on information needs relating to clinical and treatment factors. Some of the uncertainty and trauma that cancer patients face could be lessened with information that matches their needs. For example, Leydon and colleagues, (Leydon et al., 2000) demonstrated that not all patients wanted extensive information about their condition and treatment at every stage of their illness. However, patients undergoing surgery often experience considerable anxiety as a result of receiving too little information or information that they cannot fully understand (Krupat et al., 2000).

It is now recognised that there are large variations in patients' need for and satisfaction with information. The qualitative pilot study (chapter 4) emphasised that cancer patients received (or retained) different amounts of information, and there were many aspects of the treatment and recovery that many patients were not prepared for. Moreover, there were differences in the amount of information that patients required. Some patients reported that they were not able to ask questions relating to non-medical factors during the consultation, for example, how their quality of life would be impacted after treatment. It has previously been reported that unmet informational needs and low satisfaction with information provided is related to unfavourable patient outcomes, such as, lower HR-QoL, higher levels of depression and anxiety (Edwards, 1998; Mesters et al., 2001), and the use of maladaptive coping strategies. (Van der Molen,

1999) Therefore, it is clearly important to address unmet informational needs prior to treatment.

Chapter 3 highlighted the possible role of pre-treatment expectations in the judgement of post-treatment outcomes such as HR-QoL and functioning (Iversen et al., 1998; Koller et al., 2000; Mahomed et al., 2002; Staniszewska, 1999; Wan et al., 1997). Evidence from studies such as these suggests that positive expectations are associated with better health outcomes in patients with a variety of clinical conditions. In addition, investigating the influence of pre-treatment information on the formation of post-treatment expectations, may assist with the targeting of appropriate interventions to enhance outcomes.

6.2 OBJECTIVES

The objectives of this preliminary study were firstly, to explore how satisfied patients were with the information given to them about treatment and to assess whether patients' ratings significantly changed after experiencing treatment. In addition, it was anticipated that key areas could be identified that could be recommended for improvement. The second objective was to investigate the extent to which satisfaction with information pre-treatment was related to psychological constructs such as particular beliefs about the illness and treatment. The third and fourth objectives were to examine the extent to which pre-treatment factors could predict satisfaction post-treatment and investigate the extent to which patients expectations were fulfilled after treatment.

6.3 HYPOTHESES

The following hypotheses were tested in this chapter:

1) Ratings of satisfaction with information will be significantly worse after treatment has finished, than ratings of satisfaction prior to treatment.

2) Baseline psychological factors such as negative illness and treatment representations and/or the use of maladaptive coping strategies will be predictive of lower levels of satisfaction with information post-treatment.

3) Lower levels of satisfaction with information pre-treatment will be associated with unmet expectations regarding the outcome of treatment and extent of recovery at one month post-treatment and longer term (6-8 months post-treatment).

6.4 METHODS

6.4.1 Design

This chapter describes analyses using data from the prospective questionnaire based study. For further details see Chapter 5 for methods of data collection.

6.4.2 Procedure

Following patient consent, patients with a histological confirmation of carcinoma were consecutively recruited into the study. Eligible patients were recruited in the period between confirmation of diagnosis but prior to treatment. Data were collected from self-completed questionnaires and medical records. For further information on procedures see chapter 5.

6.4.3 Measures

- **The SCIP** a new measure described in the previous chapter was used to assess the extent to which head and neck cancer patients were satisfied with information received about their treatment and the consequences of treatment.
- **The Revised Illness Perception Questionnaire (IPQ-R)** (Moss-Morris et al., 2002) to elicit illness representations.
- **The Beliefs about Medicine Questionnaire (BMQ)** (Horne et al., 1999) subscales of Necessity and Concerns to measure treatment representations.

- **The Hospital Anxiety and Depression Scale (HADS)** (Zigmond et al., 1983) to measure state depression and anxiety.
- **The Life Orientation Test - Revised (LOT-R)** (Carver, 1997) to measure personality in the form of life orientation (dispositional optimism).
- **Brief COPE** (Carver, 1997) to examine coping strategies.
- **Expectations:** Three expectations regarding the experience of treatment and recovery to date were assessed at two time points: 1 month after treatment and 6-8 months after treatment. Two specific expectations were assessed: 1. Expectations regarding the treatment outcome (i.e. cosmetic and/or physical effects) and 2.expectations regarding the extent of recovery. One overall item was assessed measuring the extent to which expectations regarding the whole treatment and recovery period to date have been fulfilled. A higher score indicated that expectations had been met.

For a more detailed description of the measures and the scoring procedures, refer to chapter 5.

6.4.4 Participants

The same sample as previous, consisting of eighty-two patients newly diagnosed with a cancer of the head and neck, were recruited at the pre-treatment stage. The socio-demographic and clinical characteristics of this sample of participants versus non-participants are described in this chapter. The following analyses also uses data derived from participants followed-up one month and six-eight months after treatment. The characteristics of these samples are described in more detail in a subsequent chapter (chapter 8).

6.4.5 Statistics

The following clinical and socio-demographic variables were dichotomised: Stage of cancer (early vs. advanced), marital status (living with partner vs. living alone), ethnicity (white vs. non-white) and highest qualification (none/O' levels vs. further education and above). Site of

cancer, treating hospital and type of treatment were dummy coded. In addition, stage of cancer was also used as an ordinal measure. Skewed depression scores were successfully transformed using a square root transformation (the transformed variable is used throughout the thesis).

Both subscales of satisfaction with information were used in these analyses. Both subscales were non-normally distributed and attempts at transformation were unsuccessful. Therefore, where satisfaction with information was treated as the dependent variable (or outcome), non-parametric tests were conducted.

In order to assess the associations between baseline clinical/treatment related factors, psychological factors and baseline levels of satisfaction with information, Spearman's rank correlation coefficients were conducted.

In order to ascertain whether there were any predictive factors for low satisfaction with information either pre- or post-treatment, regression analyses were conducted. Although both subscales showed skewed distributions, subscale 1 was completely positively skewed and therefore was dichotomised into 'high' and 'low' satisfaction for use with logistic regression. Subscale 2 was more evenly distributed with a wide range of scores (see Appendix XVII) and therefore was suitable for use in linear regression models (with caution). The advantage being that the full range of scores would then be used. The two outcome measures of subscale 1 (satisfaction with amount & content of information at two different time points) were dichotomised around the median values. Low satisfaction was coded 0 and high satisfaction was coded 1. Psychological predictor variables were all assessed pre-treatment. Stepwise methods of variable entry were chosen, for both linear and logistic regression, for exploratory purposes and as hypotheses were not explicitly theory driven. This method provides the best model to fit the data (Menard, 1995) and is the most appropriate for data consisting of small samples, however, as such it may not provide the best models to generalise from. A backward

stepwise method was used for variable entry into the logistic regression as it is preferable to a forward method. This is due to suppressor effects, which occur when a predictor has a significant effect but only when another variable is held constant (Field, 2000). Backward elimination is less likely to exclude predictors involved in suppressor effects and as such reduces the probability of making a type II error than forward methods. A conditional method removes variables according to criterion.

Only factors which were established as significantly associated with satisfaction scores were entered into the regression models. Variables were entered in the regression analyses at $p<0.05$ and removed from the model at $p>0.10$.

Residual diagnostics from each of the logistic models were examined in order to determine the degree to which the models fitted the data and Hosmer-Lemeshow goodness-of-fit statistics reported. The Hosmer-Lemeshow goodness of fit test should be non-significant in order to conclude that the model fits the data to an acceptable level. Odds ratios (exp. B), 95% confidence intervals (95% CI), standard errors and Wald statistics are reported for each variable. The Nagelkerke R^2 statistic is also reported to give an estimate of the amount of variance predicted by the variables in each model, in addition to the model's coefficient which demonstrates whether the model is significant. Tests for linearity, homoscedasticity, multicollinearity, normality and independence of residuals from the linear regression models are also reported.

Relationships between satisfaction with information pre-treatment and fulfilment of expectations post-treatment were assessed with point-biserial Spearman's rank correlation coefficients (as expectations regarding specific outcomes of treatment and extent of recovery are dichotomously scored) and Spearman's rank correlation coefficients for overall

expectations regarding the whole treatment and recovery period (see chapter 5 for more details on scoring items about expectations).

The results section of this chapter is presented under four main headings (following a description of the study sample): 1) a description of levels of satisfaction pre- and post-treatment within the HNC sample; 2) the influence of clinical and treatment related variables and baseline psychological factors on pre-treatment satisfaction with information, 3) the influence of clinical and treatment related factors and pre-treatment beliefs on satisfaction with information post-treatment and 4) the extent to which pre-treatment levels of satisfaction predict whether expectations regarding treatment are subsequently fulfilled.

6.5 RESULTS

Sample characteristics

The sample consisted of 82 newly diagnosed HNC patients, which represented a 76% recruitment rate. Table 6.1 provides a breakdown of patient demographics and clinical characteristics. In the sample, 66% of participants were male, which is typical of the disease, and age ranged from 23 to 89 years, with a mean of 60 (SD=13). The majority of the sample (92%) was white. A more detailed description of each of the psychological measures (means, medians, ranges etc) can be found in Chapter 7.

Stage of disease was fairly evenly distributed with approximately half diagnosed with early stage disease (stages 1&2) and half with advanced stage disease (stages 3&4). Site of cancer was mixed but with the most common sites being tongue (ICD-10 C01&2) and larynx/ glottis (ICD-10 C32).

There were no statistical differences in age, gender, ethnicity, stage and site of cancer, between those who took part in the study and those that did not.

Some of the reasons for non-participation in this baseline sample are known. Six of the 26 non-responding patients originally consented but failed to respond. Three additional patients felt they had too little time before treatment to take part. Two patients were inpatients at the time of diagnosis and felt too unwell. Two patients were known to be alcoholics. One patient was suffering from depression at the time and another said he was too nervous and anxious to help. Two responded that they did not want to help with research at all. Reason for non-participation in the remaining nine patients was not known.

Table 6.1: Socio-demographic and clinical characteristics of responders and non-responders

Characteristic	Responders n=82 No. (%)	Non-responders n=26 No. (%)	Test statistic†
Gender			
Male	54 (66)	16 (61.5)	χ^2=0.16;p=0.69
Female	28 (34)	10 (38.5)	
Age (yrs)			
Mean (SD)	59.9 (12.5)	63.0 (13.3)	t(106)=1.08;p=0.28
Range	23-89	26-81	
Ethnicity			
White	75 (92)	23 (89)*	Cramér's V=0.17;p=0.20
Other	7 (8)	2 (8)	
Marital Status			
Single/ widowed/divorced	32 (39)	*	-
Married /cohabiting	50 (61)		
Highest Qualification*			
None	27 (33)	*	-
GCSE/O' level	15 (18)		
GCE/A' level	11 (13)		
Higher education	10 (12)		
Degree or higher	16 (20)		
AJCC Stage of cancer			
Stage 1	19 (23)*	5 (19)*	Cramér's V=0.10;p=0.96
Stage 2	20 (24)	6 (23)	
Stage 3	12 (15)	5 (19)	
Stage 4a,b & c	26 (32)	8 (31)	
Stage dichotomised			
Early stage (1 & 2)	39 (47) *	11 (42)*	Cramér's V=0.04;p=0.68
Advanced stage (3&4)	38 (47)	13 (50)	
Treatment planned			
Surgery only (S)	22 (27)	*	-
Radiotherapy only (RT)	21 (26)		
S & RT	26 (31)		
RT & Chemotherapy (CT)	9 (11)		
S & RT & CT	4 (5)		
Site of cancer (ICD-10 code)			
Lip (C00)	4 (5)	2 (8)	
Tongue (C01&2)	19 (23)	3 (12)	
Floor of mouth (C04)	12 (15)	6 (23)	
Palate (C05)	2 (2)	1 (4)	
Other& unspecified parts of mouth (C06)	4 (5)	-	Cramér's V=0.39;p=0.30
Parotid/salivary gland (C07&8)	2 (2)	-	
Tonsil (C09)	7 (9)	2 (8)	
Oropharynx (C10)	12 (15)	2 (8)	
Nasopharynx (C11)	-	2 (8)	
Hypopharynx (C13)	1 (1)	-	
Laryngeal/glottic (C32)	17 (21)	5 (19)	
Skin (non-melanoma) (C44)	2 (2)	1 (4)	
Thyroid (C73)	-	1 (8)	

* data missing/unobtainable

† Independent t-tests, Chi² tests and Cramér's V tests

6.5.1 A description of levels of satisfaction pre- and post-treatment within the HNC sample

Scores on the Satisfaction with content and amount of information subscale were negatively skewed pre- (mean=9.9; SD=9.9) and post-treatment (mean=10.1; SD=4) with ranges of 14. The median score at both time points was 11. Scores on the Satisfaction with form and timing of information were more normally distributed with a pre-treatment range of 13 (mean=28.8; SD=3.5) and post-treatment range of 21 (mean=27.4; SD=5.1).

Table 6.2 shows the number of pre-and post-treatment participants that reported that they had not received any information about areas related to treatment and recovery.

6.5.1.1 Lack of information pre-treatment

Pre-treatment perceptions of information provision demonstrated that many patients had not received (or could not remember receiving) information about a number of aspects related to their illness and treatment. One of the worst areas for receiving no information was about where to go for financial support or advice. The majority of participants in this sample (78%) were not given any information about financial support. In addition, approximately half of the sample reported they had not received any information about patient support groups for either themselves or a partner, or any information about what they should do if they experienced side-effects from the treatment. Approximately a third of patients reported that they had not been told how the treatment would affect their ability to work (35%) or whether there would be any long-term impact of the treatment on levels of functioning (32%). A large proportion of patients (43%) were also not made aware of how the treatment may affect their quality of life over the coming year.

Table 6.2: Number of participants who did not receive any information, based on SCIP items

SCIP item	Not supplied with any information pre-treatment n=82		Not supplied with any information post treatment n=68	
	n	(%)	n	(%)
Who to ask/where to go for financial support	64	(78)	41	(60)
Patient support groups for you and your partner	43	(52)	23	(34)
What you should do if you experience side-effects	41	(50)	19	(28)
Whether your treatment interferes with other medications you may be taking	37	(45)	21	(31)
How your treatment may impact on your quality of life over the next year	35	(43)	34	(50)
Whether you may need further treatment in future	30	(37)	29	(43)
The effects of treatment on your ability to work	29	(35)	21	(31)
What the risks of you experiencing complications are	29	(35)	17	(25)
The long-term impact of treatment on functioning	26	(32)	19	(28)
How long you expect recovery to take	22	(27)	18	(26)
What the risks of you experiencing side-effects are	19	(23)	4	(6)
Whether the treatment has any unwanted side-effects	18	(22)	5	(7)
How you may expect to feel immediately after treatment	15	(18)	5	(7)
The effect of treatment on your appearance	15	(18)	15	(22)

6.5.1.2 Lack of information post-treatment

Patients completed a repeat survey one month after treatment, after an appropriate time for information provision. Despite having undergone treatment, 60% of patients recruited at follow-up reported they had still not received any information regarding who to ask or where to go for financial support. Half of the patients in this sample had not discussed how their QoL may be impacted over the next year, and a third (31%) had still not been informed of how treatment may affect their ability to work. Approximately a quarter of patients reported they had not received any information on what the risks of experiencing complications had been

(25%) or what to do if they experienced side-effects (28%). The possibility of further treatment being needed in the future had not been discussed with 43% of patients and a third of patients (34%) had not received any information regarding support groups.

From both pre- and post-treatment surveys of information provision, it appears that the areas most often discussed with patients were related to the more immediate physical effects of treatment. For example, the majority of patients reported that they had received information about how they might expect to feel immediately after the treatment (82-93%), whether the treatment had any associated side-effects (78-93%), and what the risks of experiencing these side-effects were likely to be (77-94%). Information about how treatment may have affected appearance was also discussed with more frequency (82-78%) than the topics outlined in the previous paragraph.

6.5.1.3 'Is there any further information you wish you had received?'

A simple content analysis of the responses from the open ended question, 'is there any further information you wish you had received?' was conducted in order to investigate whether there were any key areas that had been omitted during the information giving process. The results from the pre- and post-treatment surveys are shown in Table 6.3. Fifty-two percent (n=43) of the pre-treatment sample reported they required no further information at the time compared with 31% of post-treatment patients, representing a reduction in 'nothing required' of 21%. This indicated that after treatment, patients required more information or realised they were missing information in hindsight. These figures did not include patients who made no response (left the section blank). Many different topics were included as suggestions for further information. Pre-treatment patients (n=82) made 16 further suggestions for information provision compared to 28 suggestions by post-treatment patients (n=68) (patients may have made more than one suggestion). Areas for further information ranged from; more detail on the physical effects of treatment to more information on the long-term effects of treatment and

the likely length of recovery (see Table 6.3). It appears from this simple content analysis that patients were not fully informed before treatment of some of the specific side-effects of treatment (both related to surgery and radiotherapy) and the severity of surgery.

Table 6.3: Content analysis of open-ended item 26 ('further information?') of the SCIP

Content*	Pre-treatment n=82	Post-treatment n=68
	n	n
No response (left blank)	23	20
'Nothing required'	43	21
Yes, more info needed (but not specified)	2	1
More written information	2	1
Information on Support groups	2	-
More procedural detail/ further treatment	3	4
Financial concerns	2	2
Length of recovery	2	3
Possibility of earlier diagnosis	1	-
Long term prognosis/prognosis if treatment fails	1	2
The name of my cancer	1	-
Information on side-effects / specific side-effects mentioned**	-	6
More contact with staff/consultant/single point of contact throughout	-	4
Long term effects	-	1
Severity of operation	-	3
General information regarding illness	-	1

*Some participants gave more than one answer
** e.g. numbness, effects on skin, soreness, no taste, shoulder problems, 'dead area' after surgery etc.

6.5.1.4 'Anything to add regarding the information you received?

A second open-ended question was asked, 'is there anything else you would like to add regarding the information you have received?' The responses are tabulated in Table 6.4. The comments related to both positive and negative aspects of information giving and care received. The content of responses to this question related more to how the information was given and provided some support for the types of items included in subscale 2 of the SCIP (the form and timing of the information) originally derived from the qualitative interviews. The most frequent comments centred around 'too little information given', and how the written

information was either 'lacking' or 'too general'. Specific areas for improvement were given as; 'nutrition', 'side-effects and symptoms', 'procedures and diagnostic tests', 'support in the form of Macmillan nurses and information about transport' and 'counselling from outside the medical profession'. Interestingly, no-one replied they had received too much information when surveyed after treatment.

Table 6.4: Content analysis of open-ended item 27 ('other comments to add?') of the SCIP

Content*	Pre-treatment n=82	Post-treatment n=68
	n	n
No response (left blank)	24	25
'Nothing to add'	42	26
'Yes' (not specified)	1	1
Too little information in general**	2	5
In addition to:		
More information on nutrition (disappointment in dietician)	-	2
More detailed information on side effects/ symptoms	-	2
Written information too general	-	1
Received no written information	2	-
Information regarding need for specific diagnostic tests	1	-
Too much information	1	-
Timing: 'Questions emerge slowly over time'	1	-
Request that info re. RT to be given after operation	1	-
Conflicting advice over procedures/ not enough information on procedures/ inconsistency	2	1
Want counselling from outside medical profession	1	-
Support provided not helpful	-	2
Practical information on transport/ local hospice help/ Macmillan nurses	-	3
Positive responses about care received	4	1

*Some participants gave more than one answer

** including 'need a comprehensive list of questions to ask based on this questionnaire'.

Levels of patient satisfaction with information about treatment and the effects of treatment pre- and post-treatment, have been described in this section. The findings have highlighted a number of significant points. Firstly, although levels of satisfaction have been found to be skewed towards higher satisfaction, variability in levels does exist demonstrating that patients needs are complex and need to be addressed on an individual basis. Although the results

shown in table 6.2 do not directly represent perceptions of satisfaction for reasons discussed later, the findings highlight areas that are commonly not included when imparting information, but that could be considered essential for the well-being of the patient. For example, information about support groups either for the patient or the partner, the effects of treatment on the ability to work, where to go for financial support and how QoL may be impacted long-term were important areas reported to be lacking.

Secondly, statistical analysis between pre-and post-treatment satisfaction scores (Chapter 5: Part 2) demonstrated a significant reduction in levels of satisfaction in key areas after treatment, as compared with scores at the pre-treatment stage. The qualitative aspects of this survey provide some support for this and highlight that patients' desire for information changes over time and particularly after experiencing treatment.

6.5.2 The influence of clinical/treatment related factors and baseline psychological factors on pre-treatment satisfaction with information

6.5.2.1 Uni-variate analyses

The influences of baseline clinical, treatment related and psychological factors on satisfaction with information were investigated using the two subscales of the SCIP. None of the socio-demographic, clinical or treatment related factors were found to be associated with either of the satisfaction with information scales, excluding one particular site of cancer: the larynx ($r=0.24;p<0.05$). This uni-variate relationship was found to be positive, indicating that patients with cancer of the larynx were more likely to be satisfied with the form and the timing of the information given to them (Table 6.5).

Table 6.5: Correlation coefficients between pre-treatment satisfaction with information and socio-demographic and clinical/treatment related factors

Variable		Subscale 1: Satisfaction with amount & content of information	Subscale 2: Satisfaction with the form & timing of information
		r	r
Socio-demographic factors			
Age		-0.06 ns	0.03 ns
Gender		-0.15 ns	-0.16 ns
Marital status		0.02 ns	-0.01 ns
Ethnicity		-0.02 ns	-0.20 ns
Qualifications		-0.04 ns	-0.11 ns
Primary treating hospital			
Guy's & St Thomas' Hospitals		-0.01 ns	-0.05 ns
Royal Sussex County Hospital		-0.14 ns	-0.03 ns
University College London Hospital		0.20 ns	0.18 ns
The Royal Marsden		0.10 ns	0.06 ns
Clinical and treatment factors			
Stage of cancer (early vs late)		0.01 ns	0.05 ns
Stage (ordinal)		0.02 ns	0.04 ns
Radiotherapy		-0.01 ns	0.02 ns
Surgery		-0.02 ns	-0.14 ns
Chemotherapy		0.09 ns	0.05 ns
Site of cancer:	Lip	-0.08 ns	-0.04 ns
	Tongue	0.02 ns	-0.10 ns
	Floor of mouth	-0.09 ns	0.17 ns
	Palate	-0.01 ns	0.04 ns
	Other sites in oral cavity	0.02 ns	0.04 ns
	Parotid	0.02 ns	0.02 ns
	Tonsil	0.06 ns	-0.10 ns
	Oropharynx	-0.17 ns	-0.17 ns
	Hypopharynx	-0.05 ns	-0.18 ns
	Larynx	0.18 ns	**0.24***
	Skin	0.10 ns	-0.15 ns

r= Spearman's rank correlation coefficient

ns= non significant; *p<0.05

Data in tables 6.5 and 6.6 based on approximately 78 patients due to missing data.

Table 6.6: Correlation coefficients between pre-treatment satisfaction with information and baseline psychological factors

Variable	Subscale 1: Satisfaction with amount & content of information	Subscale 2: Satisfaction with the form & timing of information
	r	r
Illness beliefs		
Illness identity	**-0.32****	-0.19 ns
Timeline	-0.05 ns	-0.14 ns
Consequences	-0.13 ns	-0.09 ns
Cyclical timeline	-0.19 ns	-0.10 ns
Personal control	**0.29****	**0.28***
Coherence	**0.30****	0.17 ns
Emotional representation	-0.10 ns	0.07 ns
Treatment beliefs		
Concerns	-0.05 ns	-0.13 ns
Necessity	0.01 ns	**0.28***
Personality		
Optimism	0.10 ns	0.01 ns
Mood		
Anxiety	-0.03 ns	0.03 ns
Depression	-0.06 ns	0.04 ns
Coping strategy		
Self distraction	0.06 ns	0.06 ns
Active coping	0.11 ns	0.15 ns
Denial	-0.16 ns	-0.03 ns
Substance Use	-0.05 ns	0.11 ns
Using emotional support	-0.06 ns	0.09 ns
Using instrumental support	0.14 ns	0.16 ns
Behavioural disengagement	-0.14 ns	-0.02 ns
Venting	-0.05 ns	0.03 ns
+ve reframing	0.08 ns	0.01 ns
Planning	0.08 ns	0.10 ns
Humour	-0.20 ns	-0.12 ns
Acceptance	0..06 ns	0.06 ns
Religion	**-0.27***	**-0.29****
Self-blame	0.02 ns	**0.25***

r= Spearman's rank correlation coefficient
ns= non significant; *p<0.05; **p<0.01
Data in tables 6.5 and 6.6 based on approximately 78 patients due to missing data.

Significant correlation coefficients were found between pre-treatment satisfaction with information and baseline psychological factors (Table 6.6). In particular, illness and treatment beliefs were associated with both subscales. Three illness beliefs of: illness identity (r=-0.32; p<0.01), personal control (r=0.29; p<0.01) and coherence (r=0.30; p<0.01), were significantly

associated with satisfaction with the amount and content of information. The direction of coefficients indicated that patients with more symptoms, weaker beliefs in the personal controllability of their illness and those with a weak understanding of their illness, were less likely to be satisfied with information related to content and amount. Similarly, patients reporting weaker beliefs about the personal controllability of their illness ($r=0.28$; $p<0.05$) and the necessity of treatment ($r=0.28$; $p<0.05$), were also less likely to be satisfied with the format the information was supplied on and the timing.

The only coping strategy which was significantly associated with levels of satisfaction on both subscales was the use of religion. The direction of coefficients indicated that patients reporting low levels of satisfaction, were more likely to use religion to cope ($r=-0.27$; $p<0.05$ and $r=-0.29$; $p<0.01$). Low levels of satisfaction with the form and timing of information provision were associated with feelings of self-blame ($r=0.25$; $p<0.05$). Therefore, patients reporting low levels of self-blame were less likely to be satisfied with that aspect of information.

6.5.2.2 The explanatory value of pre-treatment factors on pre-treatment satisfaction with information

For subscale 1, dividing the sample around the median, into those that were highly satisfied with information and those less satisfied, produced two fairly equal groups. Low satisfaction was indicated by scores ≤ 28, consisting of 57% of the sample ($n=44$). Table 6.7 shows the results of logistic regression. Findings indicated that only illness beliefs were significantly contributing to the overall regression model ($R^2=0.23;\chi^2=13.83;df=2;p\leq0.001$). Individuals with strong illness identities were 20% less likely to be satisfied with the amount and content of information than those with weaker identities (OR=0.8;95%CI:0.7-1.0). Conversely, those with a good understanding of their illness (high coherence) were 30% more likely to be satisfied with the information received (OR=1.3;95%CI:1.1-1.6). Both of these representations accounted for 23% of the variance in satisfaction.

Table 6.7: Variables predicting pre-treatment satisfaction with information

Outcome 1: Satisfaction with amount & content of information	*B*	SE	Wald	Exp (B)	95% CI† Lower	Upper
Beliefs						
Illness Identity	-0.22	0.10	4.96	**0.8***	0.7	1.0
Coherence	0.26	0.10	7.17	**1.3****	1.1	1.6
R^2=0.23 **Model coefficient: χ^2 =13.83;df=2;p≤0.001** **Hosmer & Lemeshow Test: χ^2 =4.77;df=8;p>0.05**						

*p<0.05; **p<0.01
†CI's have been rounded up to 1 decimal place.

Interestingly, the site of the tumour had a significant explanatory influence on satisfaction with the form and timing of information in the second (linear) regression model shown in Table 6.8 (Adj.R^2=0.22;F=7.91;df=1,71;p<0.001). In addition, stronger beliefs in the necessity of treatment to health and perceptions that the illness was within personal control were predictive of higher satisfaction with information. These three variables together accounted for 25% of the variance in satisfaction with this aspect of information provision.

Table 6.8: Variables predicting pre-treatment satisfaction with the form & timing of information

Outcome 2: Satisfaction with form & timing of information	Std β
Clinical factor	
Laryngeal cancer	**0.29****
Beliefs	
Necessity	**0.35*****
Personal control	**0.25***
R^2 =0.25; adj. R^2 =0.22; F=7.91; df=1,71 * **	

*p<0.05; **p<0.01; ***p<0.001

6.5.3 The influence of clinical/treatment related factors and pre-treatment beliefs on satisfaction with information post-treatment

6.5.3.1 Uni-variate analyses

Age was found to be associated with satisfaction with the amount and content of information after treatment ($r=0.29$; $p<0.05$), however, none of the other socio-demographic factors were found to be related to either of the subscales (Table 6.9). Regarding clinical and treatment related factors, stage of cancer, in particular, having a lower stage tumour was associated with higher satisfaction with both aspects of information ($r=-0.25$; $p<0.05$ & $r=-0.29$; $p<0.05$). Incongruously, site of cancer was associated with satisfaction, but only with particular sites. Patients diagnosed with cancer of the floor of mouth were less likely to be satisfied with the amount and content of information than all other tumour sites ($r=-0.26$; $p<0.05$), and patients diagnosed with cancer of the oral cavity (excluding tongue, palate and FOM) were more likely to be satisfied with this aspect of information than patients with all other tumour sites ($r=0.26$; $p<0.05$).

Several pre-treatment illness perceptions were found to be associated with satisfaction with information after treatment (Table 6.10). Illness identity was significantly associated with both aspects of satisfaction ($r=-0.39$; $p<0.005$ & $r=-0.43$; $p<0.001$) indicating that patients with stronger illness identities (reporting more symptoms related to HNC) were less likely to be satisfied than those with weaker illness identities. Patients with beliefs that the illness would last a long time (longer timeline perceptions) ($r=-0.32$; $p<0.01$ & $r=-0.30$; $p<0.01$), with high negative consequences to themselves ($r=-0.25$; $p<0.05$) were more likely to report low levels of satisfaction with information.

Similar to the coping strategies found to be associated with satisfaction pre-treatment, religion was again related to both subscales of satisfaction after treatment. Coefficients were negative

indicating that patients reporting the use of religion as a coping strategy were again less likely to be satisfied with either aspects of information (r=-0.25; p<0.05 & r=-0.26; p<0.05).

Table 6.9: Correlation coefficients between satisfaction with information post-treatment and socio-demographic and clinical/treatment related factors

Variable		Subscale 1: Satisfaction with amount & content of information	Subscale 2: Satisfaction with the form & timing of information
		r	r
Socio-demographic factors			
Age		**0.29***	0.07 ns
Gender		0.08 ns	0.07 ns
Marital status		-0.02 ns	-0.04 ns
Ethnicity		-0.15 ns	-0.11 ns
Qualifications		-0.20 ns	-0.03 ns
Primary treating hospital			
Guy's & St Thomas' Hospitals		-0.11 ns	-0.17 ns
Royal Sussex County Hospital		0.12 ns	0.03 ns
University College London Hospital		0.16 ns	0.20 ns
The Royal Marsden		-0.08 ns	0.17 ns
Clinical and treatment factors			
Stage of cancer (early vs. late)		-0.22 ns	-0.19 ns
Stage (ordinal)		**-0.25***	**0.29***
Radiotherapy		-0.04 ns	-0.09 ns
Surgery		-0.13 ns	-0.09 ns
Chemotherapy		0.01 ns	0.02 ns
Site of cancer:	Lip	0.13 ns	0.08 ns
	Tongue	0.11 ns	0.22 ns
	Floor of mouth	**-0.26***	-0.10 ns
	Palate	-0.10 ns	0.12 ns
	Other sites in oral cavity	**0.26***	0.06 ns
	Parotid	-0.10 ns	-0.02 ns
	Tonsil	-0.11 ns	-0.11 ns
	Oropharynx	0.08 ns	-0.20 ns
	Hypopharynx	-0.21 ns	-0.18 ns
	Larynx	0.16	0.03 ns
	Skin	-	-

r= Spearman's rank correlation coefficient
ns= non significant; *p<0.05; **p<0.01
Data in tables 6.7 and 6.8 based on approximately 60-68 patients due to missing data.

Table 6.10: Correlation coefficients between pre-treatment psychological factors and satisfaction with information post-treatment

Variable	Subscale 1: Satisfaction with amount & content of information	Subscale 2: Satisfaction with the form & timing of information
	r	r
Illness beliefs		
Illness identity	**-0.39*** **	**-0.43****
Timeline	**-0.32****	**-0.30****
Consequences	**-0.25***	-0.21 ns
Cyclical timeline	-0.03ns	0.06 ns
Personal control	-0.03 ns	0.01 ns
Coherence/understanding	0.13 ns	0.06 ns
Emotional representation	-0.20 ns	-0.19 ns
Treatment beliefs		
Concerns	-0.17 ns	-0.23 ns
Necessity	0.18 ns	0.16 ns
Personality (assessed at baseline)		
Optimism	0.07 ns	-0.02 ns
Mood		
Anxiety	-0.16 ns	-0.18 ns
Depression	-0.19 ns	-0.14 ns
Coping strategy		
Self distraction	-0.05 ns	-0.11 ns
Active coping	0.07 ns	-0.03 ns
Denial	0.004 ns	0.09 ns
Substance Use	-0.20 ns	-0.21 ns
Using emotional support	0.01 ns	-0.07 ns
Using instrumental support	-0.02 ns	-0.01 ns
Behavioural disengagement	-0.08 ns	-0.02 ns
Venting	-0.001 ns	-0.11 ns
+ve reframing	-0.08 ns	-0.10 ns
Planning	-0.03 ns	-0.02 ns
Humour	-0.11 ns	-0.04 ns
Acceptance	0.15 ns	0.18 ns
Religion	**-0.25***	**-0.26***
Self-blame	-0.05 ns	0.12 ns

r= Spearman's rank correlation coefficient

ns= non significant; *p<0.05; **p<0.01; ***p<0.005; ****p<0.001

Data in tables 6.7 and 6.8 based on approximately 60-68 patients due to missing data.

6.5.3.2 The explanatory value of pre-treatment factors on post-treatment satisfaction with information

To assess how much of the variance in satisfaction with information was due to clinical or treatment related factors, such as: type of treatment; stage of disease and treating hospital, or the types of beliefs patients had about their illness and treatment, two regression models were conducted. In subscale 1, low satisfaction was indicated by scores ≤ 28, which consisted of 51% of the sample (n=32).

Table 6.11 displays the results of logistic regression for the first subscale. Findings indicated that age, cancer site and illness beliefs were contributing to the overall regression model which accounted for 28% of the variance in satisfaction (R^2=0.28;χ^2=13.67;df=3;p<0.005). However, the only significant pre-treatment explanatory factor of low satisfaction with information after treatment, was the representations patients had about the likely duration of their illness (OR=0.7;95%CI:0.6-0.9) and beliefs about the necessity of treatment (OR=0.8;95%CI:0.6-1.0). Patients who believed prior to treatment that their illness would last a long time were 20% less likely to be satisfied with information about the content and amount of information supplied, than those who believed their illness would last a short time.

Similarly, perceptions of the illness timeline were predictive of satisfaction as assessed by subscale 2 (Table 6.12). The association was negative indicating that patients who believed prior to treatment that their illness would last a long time were also less likely to be satisfied with information about the form and timing of information supplied. In addition, patients who reported the use of religion to cope were less likely to be satisfied with this particular aspect of information. Together these two variables accounted for 20% of the variance in satisfaction.

Table 6.11: Pre-treatment variables predicting post-treatment satisfaction with amount and content of information

Outcome: Satisfaction with amount & content of information	*B*	SE	Wald	Exp (B)	95% CI† Lower Upper
Socio-demographic factors					
Age	0.05	0.03	3.58	1.1	1.0-1.1
Clinical factors					
Cancer site: Other sites in oral cavity (C06)	8.10	29.29	0.08	3292.7	-
Beliefs					
Timeline	-0.24	0.12	3.91	**0.8***	0.6-1.0
R^2=0.28 **Model coefficient: χ^2 =13.67;df=3;p<0.005** **Hosmer & Lemeshow Test: χ^2 =9.35;df=8;p>0.05**					

*p<0.05; **p<0.01; ***p<0.005
CI's have been rounded up to 1 decimal place

Table 6.12: Pre-treatment variables predicting post-treatment satisfaction with form & timing of information

Outcome 2: Satisfaction with form & timing of information	Std β
Belief	
Timeline	**-0.31****
Coping	
Use of Religion	**-0.26***
R^2 =0.20; adj. R^2 =0.17; F=7.04; df=1,58 * **	

*p<0.05; **p<0.01; ***p<0.005

6.5.4 Are pre-treatment levels of satisfaction associated with the extent to which expectations regarding the outcomes of treatment and recovery are fulfilled, after treatment?

It was hypothesised that lower levels of satisfaction with information pre-treatment would be associated with unmet expectations regarding the outcome of treatment and extent of recovery at one month post-treatment and longer term. Table 6.13 displays a summary of the three types of expectations assessed, with the degree to which patients thought these expectations had been met at two time points (1 and 6-8 months post-treatment). In order to ascertain whether the fulfilment of expectations was related to levels of satisfaction with information before treatment, correlations were conducted (Table 6.13).

6.5.4.1 Fulfilment of expectations one month after treatment

The majority of patients (65%) reported that their expectations regarding the physical and/or cosmetic outcome of treatment had either been the same or better than expected. Only 21% stated that their experiences had been worse than expected. Regarding expectations about the extent of recovery to date, 68% reported their experiences to be the same or better than expected. A quarter of patients stated that their recovery at one month post-treatment was not as they expected. Only a small fraction of patients reported having no expectations. A third of respondents reported that their overall experience of treatment and extent of recovery to date had not been as expected. Only about 10% of respondents felt that their experiences had been completely as expected.

6.5.4.2 Fulfilment of expectations 6-8 months after treatment

Ratings of the extent to which expectations had been met 6-8 months post-treatment were similar to those at one month. One slight difference could be found regarding expectations

about the cosmetic or physical outcome of treatment. More patients (49%) reported their experience at 6-8 months to be the same as expected.

Correlation coefficients (Table 6.14) indicated that patients who reported lower levels of satisfaction with information on either of the subscales before treatment, were more likely to have unmet expectations regarding treatment and recovery at one month and 6-8 months after treatment.

Table 6.13: Patients perceptions of whether expectations regarding treatment and recovery have been met

		Extent to which prior expectations were met			
		One month after treatment (n=68)		Six to eight months after treatment (n=50)	
Type of expectation assessed	**Response**	**n**	**(%)**	**n**	**(%)**
1. Cosmetic and/or physical outcome of treatment	No expectations	9*	(13)	3*	(6)
	Worse than expected	14	(21)	11	(22)
	Same as expected	25	(37)	24	(48)
	Better than expected	19	(28)	11	(22)
2. Extent of recovery to date	No expectations	5	(7)	4*	(8)
	Worse than expected	17	(25)	15	(30)
	Same as expected	25	(37)	16	(32)
	Better than expected	21	(31)	14	(28)
3. Overall expectations regarding experience of treatment and extent of recovery to date	Not as expected	22*	(32)	17	(34)
	Somewhat as expected	16	(24)	9	(18)
	Mainly as expected	22	(32)	18	(36)
	Completely as expected	7	(10)	6	(12)

* data from 1 person missing

Table 6.14: Correlation coefficients between pre-treatment satisfaction with information and the extent to which expectations were met post-treatment

Satisfaction with Information	Extent to which expectations have been met post-treatment					
	One month post-treatment			Six-eight months post-treatment		
	Cosmetic and/or physical outcome of treatment	Extent of recovery to date	Overall expectations	Cosmetic and/or physical outcome of treatment	Extent of recovery to date	Overall expectations
	r	r	r	r	r	r
Amount & content of information	0.17	0.25 (p=0.055)	**0.32***	0.17	0.11	**0.40***
Form & timing of information	0.11	0.18	0.22	-0.01	-0.09	**0.41****

r = Spearman's rank correlation coefficients

*p<0.01; **p ≤0.005

6.6 DISCUSSION

The main objectives of this chapter were related to the assessment of patients' satisfaction with information given to them before treatment, in order to identify key areas for future improvement. In addition, investigating the determinants of satisfaction with information after treatment could assist with the targeting of appropriate interventions pre-treatment, with the aim of improving individual satisfaction and enhancing patient outcomes over time.

6.6.1 The informational needs of HNC patients pre- and post-treatment

In general patients were found to be satisfied with the information given to them pre-treatment, although variability existed within the distribution of scores. Despite this good level of satisfaction, the study demonstrated that many patients had not received information about many aspects of their life expected to be affected by their illness and treatment. One of the commonest areas neglected was where to go for financial advice. The majority of the sample (78%) was not given this information and although financial advice could be considered a 'non-medical' aspect of care, treatment for HNC can last for many months and the financial repercussions can be severe if not expected. Recovery can also be lengthy and arduous, and return back to work is often delayed for many months after treatment has finished. More worrying were the results of the survey one month after treatment had finished. Of the sixty-eight patients who were recruited at one-month follow-up, 60% replied that they had still not received any information about financial support or where to go for financial advice. It could be argued that the NHS does not have a responsibility for providing information about the non-medical consequences of illness, however, patients could easily be informed of other organisations who could offer further advice or even simply advised that finances should be organised prior to treatment.

Analysis of the open-ended questions, demonstrated that patients required more information after treatment. Whether this was as a result of not being provided the information prior to

treatment, or whether needs had changed is unknown. Key topics identified for future improvement included more information on the long-term effects of treatment and length of recovery. It also appears from comments that some patients were not fully informed of common side-effects of both surgery and radiotherapy and issues relating to the anticipated severity of surgery. These findings are supported by the qualitative pilot study presented in chapter 4 (involving a different sample of patients), in which it was demonstrated that patients were not always fully informed of the likely consequences of treatment and the likelihood of complications.

Another key area for improvement was in the provision of information about support groups. Over half of the current sample had not received any information about support groups prior to their treatment and a third reported the same one month after treatment. A report by The King's Fund (1997) found that many HNC patients did not know of the existence of support groups and that some professionals did not advertise support groups as patients did not ask for them (Edwards, 1997). Local support groups known specifically for HNC patients and partners exist at many of the recruiting sites, and information about these could be supplied regardless of whether patients explicitly ask or appear to have difficulties coping.

Statistical analyses between pre- and post-treatment scores (chapter 5, part 2) demonstrated significant reductions in levels of satisfaction after treatment in key areas such as the usefulness, the detail and understanding of the information provided. The current analyses provided support that informational needs change over time and with experience of treatment (i.e. more information is generally required). Correspondingly, no participants replied that they had received too much information when asked after treatment.

Recent publications have highlighted the mismatch between the type of information HCP's provide and what patients desire. Edwards (1998) found that HNC patients wanted to be

provided with more information about the impact of their treatment, whereas clinicians were reported as concentrating too much on the specific details of the operation. Mesters et al (2001) also provided support for this view in a larger scale study of 133 patients with HNC. It was suggested that although there was a high need for information about the disease and treatment (surgery) pre-treatment, more supportive information about access to help elsewhere and solutions was required which is in concordance with the present findings. Other authors have suggested that HNC patients need and want more written information (Semple et al., 2002), similarly, Ramirez and colleagues, suggest that written detail about cancer and its management should reinforce and supplement information obtained from health professionals (Ramirez et al., 1994).

6.6.2 The role of illness and treatment perceptions and coping mechanisms on satisfaction with information

Multivariate analyses conducted to assess whether baseline factors could explain pre-treatment levels of satisfaction with information, demonstrated that illness beliefs alone explained 23% of the variance in satisfaction. Clinical and treatment related factors were not found to be significant explanatory variables. Patients with strong illness identities and those who did not have a good understanding of their illness were found to be less likely to be satisfied with the amount and content of the information provided at the time. Regarding the form and timing of the information, having cancer of the larynx, strong beliefs in the necessity of treatment to health, and perceptions that the illness was within personal control, were predictive of higher satisfaction. These variables accounted for a quarter of the variance in satisfaction with this aspect of information. It may be that patients diagnosed with cancer of the larynx were given more information due to the specific functional and emotional consequences of treatment to the throat and voice box. In addition, larynx cancer patients are generally referred to an Ear, Nose and Throat Department, which may supply information on a different basis to other units such as Departments of Oral Surgery.

Although patients in this sample were generally adherent to treatment, beliefs about the necessity of treatment have been found to be associated with adherence to treatment regimes and medication (Horne et al., 1999). It is interesting and of importance to note that levels of satisfaction were related to perceptions of the need for treatment, indicating that those with weaker beliefs in the need for treatment were less likely to be satisfied with information. This alone has important implications for the provision of clear information before beginning treatment, but equally may have important implications for subsequent levels of adherence (especially with treatments requiring high levels of adherence such as chemo- and radiotherapy).

Similar to the results from the cross-sectional analysis, baseline perceptions of timeline were also found to be predictive of satisfaction with information after treatment. Patients who believed their illness would last a long time were less likely to be satisfied with the information as assessed on both subscales. In addition, the use of religion as a coping strategy was predictive of lower levels of satisfaction with the form and timing of the information supplied. It was hypothesised that baseline psychological factors such as negative illness beliefs and the use of coping strategies would be predictive of lower levels of information post-treatment, therefore, this was rejected on the grounds that neither perceptions of a long time-line (in this case) and the use of religion as a coping strategy could be considered maladaptive.

Due to the dynamic nature of beliefs resulting from the appraisal process, beliefs could feasibly change from diagnosis throughout the period of treatment. The current study focused on whether baseline beliefs would be predictive of levels of satisfaction after treatment. The implication of determining whether certain beliefs are related to satisfaction after treatment, lies in the identification of targets for preventative interventions. The direction of causation is not really known despite using longitudinal data, however, it is plausible that beliefs could be

modified through the provision of tailored information *prior* to treatment (see section 6.6.4), leading to higher levels of satisfaction with information after treatment and better longitudinal outcomes such as fulfilment of expectations and better emotional outcomes.

6.6.2.1 Information as a coping strategy

Although few direct relationships were found between coping and satisfaction with information, information seeking behaviour or need for information could be considered a coping strategy in itself. Information seeking is used as a means of coping with and reducing stress, however, as highlighted by the current study, individuals can still feel as if their needs have not been met (Van der Molen, 1999). In addition, as supported by present findings, identification of the type of information wanted, the amount and the circumstances, can be more difficult to elucidate than just whether information is available (Bagley-Burnett, 1992).

Information could be conceptualised as a form of cognitive control as it allows patients to actively participate in their own care and decision-making. As the SRM stipulates, individuals use cognitive appraisal to evaluate the meaning of the health threat and to determine what coping resources are available to them to remedy the situation. The coping strategy used in response to the threat appraisal (in this case seeking information) is used to alter the relationship between the stressor and the individual's reaction to it. Consequently, seeking information and thus levels of satisfaction with information, could be considered a type of problem-focused coping strategy.

The lack of a direct effect between coping strategies and levels of satisfaction with information may well have been due to the coping measure used, however it may have been because satisfaction with information scores reflect a different and unrelated aspect of coping, as mentioned previously. It may be that satisfaction with information mediates the relationship between the perceptions patients have about their treatment, and outcomes such as QoL or

anxiety/ depression. Chapter 8 examines the predictors of outcomes more closely to determine whether satisfaction with information is directly related to longitudinal outcomes.

6.6.3 The relationship between pre-treatment satisfaction with information and fulfilment of expectations post treatment

It was hypothesised that lower levels of satisfaction with information would be associated with unmet expectations after treatment. It was found that patients who reported lower levels of satisfaction before treatment, were more likely to have unmet expectations overall than patients who were satisfied with the information. This relationship was strongest at six-to eight months after treatment. It is plausible that patients who did not receive enough information before treatment may have had unrealistic expectations regarding the physical outcome of treatment and time needed for recovery. However, because these associations are uni-variate other factors such as levels of optimism may be influencing expectations, or that individual's that report high levels of satisfaction are more likely to report positive outcomes such as fulfilled expectations, for consistency. It is also worth noting that the items used to measure expectations have not been previously validated.

A modest proportion (21-30%) of patients in the sample reported that their experiences had been worse than expected. Therefore, there is scope to reduce this discrepancy as much as is feasible (unforeseen complications not withstanding). One method, as previously suggested in chapter 4, could be through the provision of clear and relevant information. The fulfilment of expectations have been shown to exert significant effects on HR-QoL (Wan et al., 1997), as well as ratings of symptom severity and return to work (McCarthy et al., 2003). Therefore, it is of importance to ensure patients have a clear understanding of how their illness and treatment may affect them both short and longer term and to have achievable expectations.

6.6.4 Tailoring information to individual's needs

Chapters 4 and 6 have highlighted that HNC patients have differing needs for information and thus have demonstrated variability in their levels of satisfaction. Written materials provided for HNC patients typically consist of generic information, often in the form of pamphlets or booklets and are designed for generic use amongst all patients with HNC. Although these materials are a cost-effective method for providing valuable information, it could be argued that their one-size fits all approach is not sensitive to the variation that exists between people in their desire for and understanding of information (Kreuter, Strecher, & Glassman, 1999).

Satisfaction with information has been shown to be associated with particular patient beliefs (although the direction of causation is unclear) and has been shown to influence whether patient's expectations have been met after treatment. With this in mind and, as recommended by other authors (Newell et al., 2004; Semple et al., 2002), it would seem judicious to assess HNC patients needs for information on an individual basis.

Research focusing on tailored communication interventions to change health behaviours can easily be applied to tailored information for patients undergoing treatment for cancer. Studies have shown that matching health education materials (HEM) or messages to patient's psychological characteristics (commonly style of coping) have been found to be more effective in promoting behaviour change in a wide range of areas than non-tailored materials (Bull, Kreuter, & Scharff, 1999; Holt, Clark, Kreuter, & Scharff, 2000; Prochaska, DiClemente, Velicer, & Rossi, 1993). In addition, tailored communications may also be appropriate for HNC patients post-treatment to address any functional and emotional difficulties they may have. However, more research is needed to address under what circumstances tailored communications are most and least effective.

Technological advances mean that highly customised materials can be designed for specific individuals. Materials could be tailored to multiple aspects of the individual, providing information that fits their lives better than generic materials currently used (Holt et al., 2000). Although this is a new area for providing health education messages, it could feasibly be applied for understanding patient's individual requirements for information instead of the professional providing information on the basis of what they think the patient wants to hear.

6.6.5 Limitations

The finding of a lack of information prior to treatment is perhaps not surprising as it is possible that some of the patients may have received information after completing the questionnaire on informational needs. Information is typically 'trickled' down over time as a result of contact with different health care professionals. Due to contact with many different professionals at different sites, it has also previously been noted that this can be a source of conflicting information and omissions (Edwards, 1998). When collecting the data for the present study, an effort was made to only distribute questionnaires to patients on their second or third visit, despite the short time period between diagnosis and treatment. This was for a number of reasons, but primarily to ensure that patients had been seen by a consultant a few times in order to gain an understanding of their illness and treatment.

The finding that clinical and treatment related factors had little value in explaining variance in levels of satisfaction with information could be for a number of reasons. Firstly, patients often have multiple treatments in different departments, sometimes in different hospitals altogether, leading to multiple information sources. This also serves to obscure the effects of particular treatments and particular hospital sites on satisfaction. In addition, as mentioned elsewhere, tumour stage was derived from a mixture of pre-treatment and post-treatment observations. Often during surgery, tumours are found to be more extensive than originally staged. It was difficult to get a 'pure' sample of post-treatment tumour stages as many were missing from the

notes or pathology reports and therefore, the accuracy of the staging over all hospital sites is unknown.

It is equally likely that the patients in the post-treatment group were skewed towards higher levels of satisfaction as they were probably feeling less ill than patients who dropped out of the study. In Chapter 8, there were significant differences in stage between the sample at 6-8 month follow-up and the sample that dropped out. Unfortunately, it is not known how satisfied these patients were after treatment and it is likely that these patients are at higher risk of worse outcomes than those remaining in the study.

Patient perceptions about the illness and treatment accounted for approximately 20-28% of the variance in pre- and post treatment levels of satisfaction with information. This amount of variance explained by beliefs is in line with reported variances of approximately 20% or less from other studies (Rutter et al., 2002; Rutter et al., 2003; Scharloo et al., 2000), however, these studies have explained outcomes such as QoL or functional status and not levels of satisfaction. In terms of providing interventions targeting beliefs based on these findings, it is worth noting that these results indicate that approximately three quarters of the variance in satisfaction is due to other unknown factors, such as, personality traits other than optimism, external factors such as interaction with staff, or satisfaction with the facilities.

6.6.6 Conclusions

In order to improve service provision and care, interventions could focus on providing better information about areas indirectly affected by illness, such as financial and social support, and consequences of the treatment long term.

None of the clinical factors such as severity of cancer or treatment modality were found to influence satisfaction with information, however, beliefs and expectations were found to be

related to reports of satisfaction with information. Psychological aspects such as these, are however, open to modification unlike clinical related factors. Patient perceptions, in particular beliefs about the necessity of treatment, personal control, likely timeline of the illness and illness identity could be addressed through tailored interventions aimed at modifying these key perceptions and increasing levels of coherence regarding the illness and treatment overall.

An additional positive aspect of enhancing patient satisfaction with information, by providing a good match between the provision of information and patients requirements, is the promotion of partnership between the patient and the health care professional. The need for good communication between health professionals and patients is emphasised in current NHS policy (NHS Centre for Reviews and Dissemination, 2000) and also serves to aid the decision making process by empowering the patient (Grahn, 1996).

It has been suggested that low levels of satisfaction with information are associated with worse outcomes such as QoL (Yu et al., 2001), and this relationship has been preliminary explored during psychometric testing of the SCIP instrument (chapter 5 part 2). Further research to investigate whether pre-treatment levels of satisfaction with information are influential on long-term outcomes, such as QoL and depressive symptoms, is further investigated in chapter 8.

CHAPTER 7

PRE-TREATMENT RELATIONSHIPS BETWEEN QOL MEASURES

7.1 INTRODUCTION

Chapter 2 demonstrates the wealth of literature published describing HR-QoL in HNC patients. However, studies of QoL in this patient group have made the assumption that a *standard* set of circumstances is required for optimal well-being, but measures of physical functioning, pain, psychological discomfort, social limitations and handicap do not take into account the fact that many patients may have come to terms with their limitations and consequently these areas of measurement may have little impact on levels of satisfaction or adaptation. Within this context, there has been little published on assessment of individualised QoL (i.e. how patients perceive their QoL with respect to areas most important to them) and how it compares with traditional measures.

Standardised HR-QoL has been shown to vary with time and treatment modality (de Graeff et al., 2000a; Hammerlid et al., 1997b) but why those with similar stages of disease and treatment should experience different levels of quality of life is unclear. However, chapter 3 highlights that there is enormous variation in the ways patients adjust to illness and the nature of this adjustment may be crucial in determining psychological and physical health outcomes. In addition, this variation is not necessarily due to clinical factors such as illness severity. To gain a better understanding of how HNC and its treatment influences QoL, a theoretical framework is required.

The Self-Regulation Model (Leventhal et al., 1980; Leventhal, Diefenbach, & Leventhal, 1992) provides a framework for understanding how patients perceive and adapt to a health threat, in this case, a cancer diagnosis and its treatment (see Chapter 3 for an in-depth discussion of this model). The framework suggests that four broad classes of factors influence patient

judgements and behaviour: the *cognitive representation* of the disease threat (i.e. the beliefs which patients have about their illness and treatment); *the affective reaction* (i.e. the emotional reaction to the illness); the *coping mechanisms* to deal with the health threat and the emotions elicited by the threat; and *contextual factors* such as social roles and cultural/ societal norms.

There have been no published studies assessing the role of psychological factors on outcome from the perspective of HNC patient beliefs about the illness and treatment, and thus the main implications for this study were two-fold. Firstly, it was anticipated that the study would lead to a better understanding of the types of beliefs HNC patients had prior to treatment and demonstrate how these related to outcome. Secondly, potentially modifiable psychological factors found to be related to outcome could therefore be used as a basis for future intervention in order to maximise pre-treatment QoL. Specification of variables within the SRM framework lead to the development of hypotheses to test and further our understanding of QoL in patients with HNC.

7.2 AIMS

Therefore, this chapter seeks to address the issues outlined in the introduction. The results section has been divided into four parts relating to each of the main aims:

1. To assess the extent to which measures of QoL are related to each other.

2. To assess the extent to which psychological variables can explain different QoL outcomes: a) standardised HR-QoL and b) individualised QoL.

3. To establish baseline levels of depression and anxiety in this sample of patients.

4. To assess the extent to which psychological variables can explain levels of emotional adaptation (i.e. depression and anxiety).

7.3 HYPOTHESES

The following null hypotheses were tested in this chapter:

1: There will be no relationship between standardised assessments of HR-QoL and individualised QoL.

2a: Illness and treatment beliefs will not explain a significant amount of variance in standardised HR-QoL.

2b: Illness and treatment beliefs will not explain a significant amount of variance in individualised QoL.

3a. Depression will not explain a significant amount of variance in standardised HR-QoL.

3b. Depression will not explain a significant amount of variance in individualised QoL.

4: Illness and treatment perceptions pre-treatment will not be associated with utilising adaptive coping strategies (e.g. active coping, positive reframing, planning, acceptance, use of emotional support and use of instrumental support) at baseline.

5a. Illness and treatment beliefs will not explain a significant amount of variance in depression.

b. Illness and treatment beliefs will not explain a significant amount of variance in anxiety.

7.4 METHOD

7.4.1 Design

This chapter describes the results of analyses using cross-sectional data assessed at baseline (after diagnosis but prior to treatment).

7.4.2 Procedure

Following patient consent, patients with a histological confirmation of carcinoma were consecutively recruited into the study. Eligible patients were recruited in the period between confirmation of diagnosis but prior to treatment. Data were collected from self-completed questionnaires and medical records. For further information on procedures see chapter 5.

7.4.3 Measures

Quality of life:

- **EORTC QLQ-C30** (Aaronson et al., 1993).
- **SF-12v2** (Ware et al., 2002).
- **Patient Generated Index** (Ruta et al., 1994).

Psychological measures

- **IPQ-R** (Moss-Morris et al., 2002) to elicit illness representations.
- **BMQ-Specific** (Horne et al., 1999) subscales of Necessity and Concerns to measure treatment representations.
- **Brief COPE** (Carver, 1997) to examine coping strategies.
- **LOT-R** (Scheier et al., 1994) to measure personality in the form of life orientation (dispositional optimism).
- **HADS** (Zigmond et al., 1983) to measure state depression and anxiety.

Full descriptions of these measures can be found in chapter 5, methodology part 1.

Socio-demographic variables of: age, gender, socio-economic status, marital status and ethnicity were assessed as described in the methods section (chapter 5). Clinical factors such as site and stage of cancer, and treatment planning were also assessed as described in chapter 5.

7.4.4 Participants

A sample of eighty-two newly diagnosed HNC patients were recruited into the study prior to treatment (T1) out of 108 approached, giving approximately a 76% recruitment rate (see Methods: Table 5.1).

7.4.5 Statistical analysis

QoL scores were standardised as per recommendations (see chapter 5). The following clinical and socio-demographic variables were dichotomised: Stage of cancer (early vs. advanced), marital status (living with partner vs. living alone), ethnicity (white vs. non-white) and highest qualification (none/ O'levels vs. further education and above). Cancer sites were dummy coded into variables of: lip; tongue; FOM; palate; parotid gland; tonsil; oropharynx; hypopharynx; larynx; skin and other.

Relationships between individualised QoL and standardised HR-QoL measures were analysed using Spearman's rho correlation coefficients. Non-parametric correlations were used at this stage as some of the SF-12 and EORTC QLQ-C30 subscales were non-normally distributed and could not be successfully transformed. Main outcome variables (PGI, EORTC QLQ-C30 Global QoL and SF-12 PCS & MCS) used in further analyses in this chapter could be considered normally distributed.

Relationships between main outcome variables and independent variables were analysed using Pearson's product moment correlation coefficients and variables found to be significantly associated ($p \leq 0.05$) were entered into linear regression models using the Stepwise method. The stepwise method was chosen as most appropriate for statistically reducing the number of variables entered into the final model. Models were then re-run entering only significant contributing factors. Socio-demographic variables were entered first, followed by clinical variables, followed by illness and treatment representations as indicated by the correlational analyses.

7.3 Results

Sample characteristics

The sample consisted of 82 newly diagnosed HNC patients (see Chapter 6 for a detailed breakdown of sample characteristics).

Preliminary analysis

7.3.1 Investigating the relationships between individualised QoL and standardised HR-QoL

Tables 7.1 to 7.4 present the means (SD), medians and ranges for individualised QoL and standardised measures of HR-QoL. All domains proved reliable in this sample.

Table 7.1: Mean (SD), median and range for individualised QoL (n=59)

Patient Generated Index	Mean (SD)	Median	Range
	4.27 (2.26)	4	0-10

Cronbach's alpha cannot be computed as overall QoL only consists of 1 final score.

Although scores on the PGI were within an acceptable range for a normal distribution, the mean and median values were slightly negatively skewed. The score is intended to represent the extent to which reality matches patient's expectations i.e. their perceived QoL, in the areas of life that are most important to them. Therefore, values indicated that patient's functioning in the most important areas of life, was perceived to be on the low side (Table 7.1).

Table 7.2 presents descriptive data for cancer specific HR-QoL as measured by the EORTC QLQ-C30. Higher scores on the functioning domains indicate better pre-treatment QoL. Unlike the scores for individualised QoL, all functional scales were positively skewed towards better functioning. Physical functioning scores were the highest and the most skewed indicating

that pre-treatment, patient's physical functioning was not very impaired. Despite this, mean scores for Global QoL and Emotional Functioning were found to be the lowest. As expected, mean values for general symptom scales and symptom items were low indicating that not many general symptoms were currently being experienced.

Table 7.2: Means (SD), medians, range and Cronbach's alpha values for cancer specific HR-QoL

EORTC QLQ-C30 Domain	Mean (SD)	Median	Range	Cronbach's α
Global QoL **(n=82)**	62.2 (23.69)	66.67	0-100	0.87
Functional Domains:				
Emotional Functioning (n=82)	65.48 (27.72)	75	0-100	0.89
Cognitive Functioning (n=82)	75.81 (28.47)	83.33	0-100	0.71
Physical Functioning (n=81)	85.56 (18.87)	93.33	26.7-100	0.78
Social Functioning (n=82)	74.39 (27.24)	83.33	0-100	0.70
Role Functioning (n=80)	78.13 (30.88)	100	0-100	0.84
Symptom Scales:				
Fatigue (n=81)	28.19 (26.73)	22.22	0-100	0.87
Nausea and vomiting (n=81)	9.05 (19.37)	0	0-100	0.86
Pain (n=82)	25.41 (25.82)	16.67	0-100	0.81
Symptom items‡:				
Dyspnoea (n=81)	16.05 (25.88)	0	0-100	N/A
Insomnia (n=80)	32.08 (34.14)	32.08	0-100	N/A
Appetite loss (n=81)	27.16 (33.38)	0	0-100	N/A
Constipation (n=82)	17.07 (28.32)	0	0-100	N/A
Diarrhoea (n=82)	9.35 (21.77)	0	0-100	N/A
Financial Difficulties (n=82)	32.52 (38.48)	16.67	0-100	N/A

‡Cronbach's alpha cannot be computed as symptom items consist of 1 item only.

Similarly, the mean values for head and neck cancer specific symptom scales and symptom items (Table 7.3) were negatively skewed indicating that not many symptoms related to head and neck cancer were currently being experienced at that time. However, the use of painkillers

was positively skewed indicating that high levels of painkillers were generally being used by this sample, which may have been responsible for negatively skewing specific and general symptom scales.

Table 7.3: Means (SD), medians, range and Cronbach's alpha values for head and neck cancer specific HR-QoL

EORTC QLQ-H&N35 Domain	Mean (SD)	Median	Range	Cronbach's α
Symptom Scales (n=82):				
Pain	29.74 (25.02)	25	0-100	0.78
Swallowing	14.53 (21.11)	8.33	0-100	0.84
Senses problems	12.2 (20.96)	0	0-83.33	0.7
Speech problems	19.44 (22.9)	11.11	0-100	0.71
Trouble with social eating	20.56 (26.58)	8.33	0-100	0.87
Trouble with social contact	10.81 (18.01)	0	0-73.33	0.85
Less sexuality*	28.89 (36.59)	0	0-100	0.93
Symptom items‡:				
Teeth (n=81)	16.05 (31.23)	0	0-100	N/A
Opening mouth (n=82)	25.61 (34.47)	0	0-100	N/A
Dry mouth (n=81)	23.05 (29.17)	0	0-100	N/A
Sticky saliva (n=81)	15.64 (27.43)	0	0-100	N/A
Coughing (n=82)	29.67 (27.72)	33.33	0-100	N/A
Felt ill (n=82)	18.29 (25.74)	0	0-100	N/A
Pain killers (n=81)	61.73 (48.91)	100	0-100	N/A
Nutritional supplements (n=81)	22.22 (41.83)	0	0-100	N/A
Feeding tube (n=81)	3.7 (19)	0	0-100	N/A
Weight loss (n=81)	27.16 (44.76)	0	0-100	N/A
Weight gain (n=81)	8.64 (28.27)	0	0-100	N/A
Shoulder function$	9.45 (19.50)	0	0-75	N/A

‡Cronbach's alpha cannot be computed as symptom items consist of 1 item only.
* Data from 7 patients missing
$ Extra item added to questionnaire (see methods chapter)

Table 7.4: Means (SD), medians, ranges and Cronbach's Alpha values for generalised HR-QoL (n=82)

SF-12v2 Domain	Mean (SD)	Median	Range	Cronbach's α
Mental Health	63.11 (23.73)	62.5	0-100	0.75
Role Emotional	75.61 (28.73)	87.5	0-100	0.88
Social Functioning‡*	75.31 (29.71)	75	0-100	N/A
Role Physical	69.82 (29.26)	75	0-100	0.9
General Health‡	60.12 (29.43)	60	0-100	N/A
Bodily Pain‡	74.7 (28.73)	75	0-100	N/A
Vitality‡	50 (27.5)	50	0-100	N/A
Physical Functioning*	77.74 (29.14)	100	0-100	0.79
Mental Component Summary (MCS)*	45.97 (11.72)	48.97	10-69	N/A
Physical Component Summary (PCS)*	47.41 (10.22)	49.53	10-68	N/A

‡Cronbach's alpha cannot be computed as domains only consist of 1 item.
* data from 1 person missing

Regarding generalised HR-QoL, high levels of functioning were also evidenced (Table 7.4). Again, functional domains were positively skewed, in particular role emotional functioning and physical functioning. Vitality and mental health were found to be lowest but within the range of a normal distribution. Both the Mental Component Summary scores and Physical Component Summary scores were normally distributed after the removal of outliers.

As shown in Table 7.5, standardised HR-QoL and individualised QoL measures were only partially correlated and therefore, the null hypotheses 'there will be no relationship between standardised assessments of HR-QoL and individualised QoL' was rejected. The PGI was only significantly correlated with EORTC QLQ-C30 domains of: Global QoL ($r=0.39, p<0.005$); Emotional Functioning ($r=0.38$, $p<0.005$); Cognitive Functioning ($r=0.39$, $p<0.005$), and similarly with the SF-12 Mental Component Scale ($r=0.44, p<0.001$) and domains of: Mental Health ($r=0.38, p<0.005$); Role Emotional ($r=0.47$, $p<0.001$); Social Functioning ($r=0.30$,

p<0.05) and Role Physical (r=0.35, p<0.01). The two HR-QoL measures were highly correlated with each other as expected.

Table 7.5: Correlations between individualised QoL and standardised HR-QoL measures

	PGI (individualised QoL)	
HR-QoL Domain	**Correlation coefficient**	**significance**
EORTC QLQ-C30		
Global QoL	0.39	p<0.005
Emotional Functioning	0.38	p<0.005
Cognitive Functioning	0.39	p<0.005
Physical Functioning	0.04	n/s
Social Functioning	0.11	n/s
Role Functioning	0.18	n/s
SF-12		
Mental Component Scale (MCS)	0.44	p<0.001
Physical Component Scale (PCS)	0.14	n/s
Mental Health	0.38	p<0.005
Role Emotional	0.47	p<0.001
Social Functioning	0.30	p<0.05
Role Physical	0.35	p<0.01
General Health	0.24	n/s
Bodily Pain	0.26	n/s
Vitality	0.20	n/s
Physical Functioning	0.01	n/s

7.3.2 Relations between pre-treatment representations regarding HNC and treatment, QoL outcomes and coping strategy employed

The majority of the scales had acceptable levels of internal reliability (Table 7.6). However, Brief COPE scales of self-distraction, use of instrumental support, behavioural disengagement and venting proved unacceptably low. As these scales only consist of 2 items each, deletion of unreliable items could not be conducted.

Mean values indicated that levels of Illness Identity were low in this sample and perceptions of the consequences of the illness, the emotional representations and perceptions of illness coherence were fairly high at the pre-treatment stage.

Beliefs about the necessity of treatment were very high in this sample, however, concerns about the treatment were a lot lower.

The reported use of coping strategies was highest for active coping, use of emotional support and acceptance, all of which are considered adaptive coping strategies. The use of maladaptive coping strategies such as, substance use and behavioural disengagement, were reported as low.

Levels of anxiety and depression were generally low, however, mean levels of anxiety were higher than levels of depression.

Table 7.6: Means (SD), medians, ranges and Cronbach's Alpha values for illness representations, treatment beliefs, coping strategies, anxiety, depression and optimism scores

Psychological Factor	Mean (SD)	Median	Range	Cronbach's α
IPQ-R subscale:				
Illness Identity (n=79)	3.95 (3.15)	3	0-12	N/A
Timeline (n=81)	7.54 (2.52)	8	3-15	0.88
Consequences (n=81)	9.28 (2.68)	9	3-15	0.69
Timeline Cyclical (n=79)	7.63 (2.68)	7	3-15	0.74
Personal Control (n=80)	6.88 (1.70)	7	3-10	0.61
Illness Coherence (n=81)	10.05 (2.97)	10	3-15	0.78
Emotional representations (n=80)	9.83 (3.1)	10	3-15	0.87
BMQ-Specific subscale:				
Necessity (n=79)	21.05 (2.72)	20	14-25	0.75
Concerns (n=80)	12.92 (3.46)	13	4-20	0.75
Brief COPE subscale (n=80):				
Self Distraction	4.16 (1.9)	4	2-8	0.53
Active Coping	5.19 (1.9)	5	2-8	0.61
Denial	3.53 (1.83)	3	2-8	0.76
Substance Use	3.1 (1.85)	2	2-8	0.92
Use of Emotional Support	5.46 (1.98)	5	2-8	0.76
Use of Instrumental Support	4.15 (1.62)	4	2-8	0.58
Behavioural Disengagement	2.61 (1.11)	2	2-6	0.29
Venting	3.28 (1.51)	3	2-8	0.49
Positive Reframing	4.19 (1.98)	4	2-8	0.69
Planning	4.65 (2.13)	4	2-8	0.78
Humour	4.16 (2.21)	3	2-8	0.86
Acceptance	6.25 (1.78)	7	2-8	0.62
Religion	3.35 (1.83)	2	2-8	0.69
Self-Blame	3.73 (2.28)	3	2-14	0.76
HADS subscale (n=81):				
Anxiety	7.89 (26.9)	7	0-20	0.89
Depression	3.85 (3.45)	3	0-11	0.81
LOT-R (n=78)	22.58 (4.88)	23	11-30	0.74

7.3.2.1 Assessing the extent to which psychological variables explain standardised HR-QoL

Analysis indicated that the four different measures of HR-QoL were explained by different factors. Tables 7.7 to 7.9 present the standardised betas for each of the variables found to be significant contributors in each model. None of the clinical or socio-demographic variables, apart from age, proved significant explanatory factors for any of the variance in HR-QoL.

7.3.2.1.1 SF-12v2: Physical Component Summary (PCS) scores

Illness Identity (IPQ-R), age and depression together explained 35% of the variance in PCS scores, with depression explaining the largest amount of variance (Table 7.7). The direction of the coefficients indicated that a lower illness identity, younger age and lower levels of depression were associated with perceptions of better functioning on physical aspects of QoL.

Table 7.7: Explanatory factors of PCS

Explanatory factor	Std β
Illness Identity (IPQ-R)	-0.30*
Depression (HADS)	-0.37**
Age	-0.25*

Overall Model: $R^2 = 0.38$; *adj.* $R^2 = 0.35$; $F = 14.81$; $df = 3,73$ **
*$p<0.01$, **$p<0.005$

Although, this model proved highly significant (adj. $R^2 = 0.35$; $F = 14.81$; $df = 3,73$; $p<0.005$), again the distribution of standardised residuals from the PCS regression model plotted against standardised predicted values were not equal and therefore the model should be interpreted with some caution.

7.3.2.1.2 SF-12v2: Mental Component Summary (MCS) scores

Mental component scale scores could be significantly explained with a three-factor model consisting of depression, emotional representations and using substances such as alcohol and

drugs, as a coping strategy (Table 7.8). This model explained 54% of the variance in mental components of QoL (*adj.* R^2 *=0.54; F=31.21; df=3,73;* p<0.005).

Table 7.8: Explanatory factors of MCS

Explanatory factor	Std β
Depression (HADS)	-0.54**
Emotional representation (IPQ-R)	-0.20*
Substance Use (COPE)	-0.17*

Overall Model: R^2 *=0.56; adj.* R^2 *=0.54; F=31.21; df=3,73* **
*p<0.05, **p<0.005

Relationships between variables were inverse, indicating that higher levels of depression, stronger emotional representations and higher levels of reported substance use were associated with poorer mental QoL.

7.3.2.1.3 EORTC QLQ-C30 Global QoL/health status

A model with four factors significantly explained approximately 50% of the variance in pre-treatment Global QoL (Table 7.9). Perceptions of the illness lasting a long time, a strong illness identity, use of instrumental support such as getting advice from other people and high levels of self-blame were all associated with lower levels of global QoL (adj. R^2 =0.48; F=18.75; df=4,73; p<0.005).

Table 7.9: Explanatory factors of Global QoL/health status

Explanatory factor	Std β
Timeline (IPQ-R)	-0.20*
Illness Identity (IPQ-R)	-0.38**
Use of Instrumental Support (COPE)	-0.25**
Self-blame (COPE)	-0.29*

Overall Model: R^2 *=0.51; adj.* R^2 *=0.48; F=18.75; df=4,73* **
*p<0.05, **p<0.005

It was hypothesised that illness and treatment beliefs would not explain a significant amount of variance in standardised HR-QoL, however, Illness Identity proved a significant explanatory variable of both the Physical Component Scale of the SF-12 and global QoL of the EORTC QLQ-C30. In addition, perceptions of the likely duration of the illness significantly impacted on global QoL. Mental components of QoL (as measured by the SF-12) could be explained by the emotional representations patients had about their cancer. Beliefs about treatment were not, however, associated with pre-treatment HR-QoL.

The null hypothesis that depression would not explain a significant amount of variance in standardised HR-QoL was also rejected, as a significant amount of the variance in both MCS and PCS (SF-12) could be explained by depression.

7.3.2.2 Assessing the extent to which psychological variables explain individualised QoL.

Anxiety was the sole explanatory factor remaining when entered into the final regression model (Table 7.10). 16% of the variance in PGI scores could be explained by anxiety. The negative association indicated that higher levels of anxiety were associated with lower levels of individualised QoL.

Table 7.10: Explanatory factor of individualised QoL

Explanatory factor	Std β
Anxiety (HADS)	-0.42**

Overall Model: $R^2 = 0.17$; *adj.* $R^2 = 0.16$; $F = 10.64$; $df = 1,57$ **
**$p<0.005$

It was hypothesised that illness and treatment beliefs would not explain a significant amount of variance in individualised QoL. This was accepted as only anxiety proved to be a significant explanatory variable prior to treatment.

There were no significant relationships between personality (LOT-R) and any of the outcome measures or socio-demographic factors ($p>0.05$).

7.3.2.3 The relationship between pre-treatment illness and treatment representations and coping

Table 7.11 presents the correlation coefficients between illness and treatment representations and coping strategies used. Patients with more negative perceptions regarding the consequences of the illness were more likely to use emotional support ($r=0.24;p\leq0.05$) and planning strategies ($r=0.32;p\leq0.01$) in order to cope with the illness. Beliefs about the extent of personal control over the illness were also positively associated with planning strategies ($r=0.25;p\leq0.05$) and active coping ($r=0.27$; $p\leq0.05$). This indicated that patients who had strong beliefs about the personal controllability of their cancer were more likely to cope by devising strategies to deal with the problem and taking action.

Emotional representations were also positively related to active coping ($r=0.29;p\leq0.01$) and positive reframing ($r=0.25$; $p\leq0.01$), therefore the stronger the emotional representations of the illness, the more likely the patient would engage in taking action to address the stressful situation or try to think of something beneficial to come out of the situation.

Beliefs about the necessity of treatment were positively associated with active coping ($r=0.31$; $p\leq0.01$) and use of emotional support ($r=30;p\leq0.01$), whereas strong concerns about treatment were related to more positive reframing ($r=0.26$; $p\leq0.05$).

It was hypothesised that more negative pre-treatment illness and treatment perceptions would not be associated with utilising adaptive coping strategies (e.g. active coping, positive reframing, planning, acceptance, use of emotional support and use of instrumental support) at baseline'.

This was rejected. However, it is also worth noting that more maladaptive coping styles were also positively associated with more negative illness and treatment perceptions than the adaptive coping strategies outlined above. For example, higher levels of denial, substance use and venting were associated with perceptions of more negative consequences, greater concerns regarding treatment, and a greater emotional response to the illness. High levels of denial were also associated with lower levels of understanding (coherence) regarding their illness.

There were no significant relationships between optimism (LOT-R) and coping strategies used ($p>0.05$). However, significant relations were found between optimism and IPQ-R Timeline ($r=-0.24, p<0.05$) and Personal Control ($r=0.27, p<0.05$), indicating that patients with higher levels of dispositional optimism had strong perceptions of personal control and beliefs that their illness would not last a long time.

Table 7.11: Correlation coefficients between illness and treatment representations and coping strategies

IPQ-R & BMQ-Specific factors	Coping Strategies measured by Brief COPE													
	Self-distraction	Active coping	Denial	Substance Use	Use of emotional support	Use of instrumental support	Behavioural disengage-ment	Venting	+ve reframing	Planning	Humour	Acceptance	Religion	Self-blame
Illness Identity (IPQ-R)	**0.30****	0.04	**0.24***	0.18	0.13	0.12	0.21	**0.23***	0.08	0.08	0.09	-0.20	0.14	0.15
Timeline (IPQ-R)	0.20	0.004	0.15	0.07	0.09	0.07	0.02	-0.05	-0.06	0.19	0.05	-0.19	0.08	0.04
Conse-quences (IPQ-R)	**0.32****	0.11	**0.32****	**0.28****	**0.24***	0.06	-0.04	**0.26***	0.17	**0.32****	0.17	-0.08	0.16	0.22
Cyclical timeline (IPQ-R)	0.12	-0.06	**0.26***	-0.06	-0.11	-0.13	**0.23***	0.16	-0.03	0.03	0.04	-0.21	0.22	0.13
Personal Control (IPQ-R)	0.13	**0.27***	-0.07	-0.01	0.17	0.05	-0.13	0.01	0.05	**0.25***	-0.002	0.17	-0.08	**0.22***
Coher-ence (IPQ-R)	-0.15	0.16	**-0.37****	-0.07	-0.02	0.04	-0.07	-0.11	-0.19	0.05	-0.13	-0.10	-0.20	0.19
Emotion-al (IPQ-R)	**0.28***	**0.29****	**0.34****	**0.38****	0.08	0.11	0.14	**0.32****	**0.25****	0.20	-0.09	-0.07	**0.32****	**0.36****
Concerns (BMQ)	**0.25***	0.17	**0.40****	**0.34****	0.16	0.18	-0.09	**0.33****	**0.26***	0.21	0.05	0.03	**0.34****	0.07
Necessity (BMQ)	0.15	**0.31****	0.03	0.22	**0.30****	0.09	-0.04	0.16	0.17	0.22	-0.20	0.12	-0.08	**0.32****

*$p \leq 0.05$, **$p \leq 0.01$

7.3.3 Baseline levels of depression and anxiety

Pre-treatment levels of anxiety and depression in this patient group were established in order to be able to compare and control for this in later analyses.

The cut-off score for a possible case of depression using the HADS is 8 to 10 (inclusive) and >10 points for probable depression.

Table 7.12: Pre-treatment levels of depression and anxiety in sample of HNC patients

HADS domain		Within normal limits	Possible clinical case	Probable clinical case
		n (%)	n (%)	n (%)
Anxiety	Male	30 (56)	10 (18)	14 (26)
	Female	13 (48)	4 (15)	10 (37)
	Total	43 (53)	14 (17)	24 (30)
Depression	Male	44 (82)	8 (14)	2 (4)
	Female	21 (78)	4 (15)	2 (7)
	Total	65 (80)	12 (15)	4 (5)

Levels of anxiety were reported to be higher than levels of depression prior to treatment, with 47% of the sample scoring within the limits for possible or probable clinical anxiety, but only 20% scoring within the same limits for clinical depression. Independent samples t-tests indicated there was no significant gender difference between depression scores ($t(79)=0.19, p>0.05$) or anxiety scores ($t(40.45)=-1.11, p>0.05$).

7.3.4 Depression and anxiety as outcome measures

Due to the complex and dynamic relationship between depression and QoL (discussed in chapter 2 part 1) it was decided that it would be informative to investigate what factors (aside from QoL) could explain variance in patient's levels of depression and anxiety.

Approximately 50% of the variance in depression scores could be explained by anxiety, perceptions of illness identity and maladaptive feelings of self-blame (*adj.* $R^2=0.53$; $F=30.28$;

df=3,74; p<0.005). The relationship between these three variables and depression was positive indicating that higher scores on these measures were associated with higher levels of depression (Table 7.13).

Table 7.13: Explanatory factors of depression

Explanatory factor	Std β
Anxiety (HADS)	0.46**
Illness Identity (IPQ-R)	0.32**
Self-Blame (COPE)	0.20*

Overall Model: R^2 *=0.55; adj.* R^2 *=0.53; F=30.28; df=3,74* **
*p<0.05, **p<0.005

A model consisting of emotional representations, depression, and the maladaptive coping strategies of venting and self-distraction explained 67% of the variance in pre-treatment anxiety (Table 7.14). Emotional representations of the illness explained the most variance and the direction of the coefficient indicated that stronger emotional representations were associated with higher levels of anxiety.

Table 7.14: Explanatory factors of anxiety

Explanatory factor	Std β
Emotional representation (IPQ-R)	0.46**
Depression (HADS)	0.31**
Venting (COPE)	0.19*
Self-Distraction (COPE)	0.15*

Overall Model: R^2 *=0.69; adj.* R^2 *=0.67; F=40.07; df=4,73* **
*p<0.05, **p<0.005

Similar to the QoL models, the models of depression and anxiety also proved highly significant at p<0.005, however, the distributions of standardised residuals from each regression model plotted against standardised predicted values were not normal and therefore these results also need to be interpreted with caution.

Null hypotheses 5a and b were subsequently rejected, as Illness Identity and emotional representations were significant explanatory variables of anxiety and depression. Treatment beliefs did not explain a significant amount of variance in pre-treatment anxiety or depression.

7.4 DISCUSSION

Although standardised (or traditional) HR-QoL measures are often used with HNC patients within a clinical setting, it has been suggested that they fail to capture the individual's sense of 'quality of life'. This is because they focus on the individual's perception of QoL but only related to pre-selected domains. In contrast, patient generated outcome (individualised QoL) attempts to capture aspects of QoL that are most important to the individual at that particular time point. Given the interest in the use of individualised measures in clinical trials (Campbell et al., 2000; Patel et al., 2003) and with cancer patients in general (Camilleri-Brennan et al., 2002; Lindblad, Ring, Glimelius, & Hansson, 2002; Waldron, O'Boyle, Kearney, Moriarty, & Carney, 1999), the use of patient reported outcomes could be beneficial in the area of HNC. There have been no published studies assessing the individualised QoL of HNC patients, therefore, little is known about how it compares with standardised HR-QoL.

In the present study it was hypothesised that there would be no relationship between standardised assessments of HR-QoL and the individualised measure of QoL due to their conceptual differences. The results of our study suggest that there is partial overlap between these measures and that the main overlap appears to exist between individualised QoL and the cognitive, emotional and mental health QoL domains of the standardised measures. Therefore, the first null hypothesis was rejected.

In contrast to our results, the PGI has been found to be more related to physical aspects of HR-QoL in other patient groups. For example, in a study of severely disabled patients with multiple sclerosis, results indicated that QoL as assessed by the PGI was dependent upon a

person's level of physical ability, as opposed to an alternate patient-centred measure (the SEIQoL) which appeared to be more related to feelings of health and vitality,(Lintern et al., 2001) similar to the PGI in our study.

The PGI has been found to be more responsive to change than the SF-36 and the EORTC-QLQ-C30 in surgical patients with rectal cancer (Camilleri-Brennan et al., 2002) and thus may prove to be a more meaningful assessment tool for the outcome of patients with cancer.

The Self-Regulation Model (Horne et al., 1999; Leventhal et al., 1980; Leventhal et al., 1992) proposes that in response to a health threat, such as the diagnosis of cancer, individuals develop their own beliefs and emotional responses about their illness and treatment, which then influence the coping procedures they adopt. These beliefs, emotional responses and coping strategies then influence the outcome, which, in this study, were perceptions of QoL. As this is a constant process of reappraisal, patient beliefs and coping strategies may change over time. In the present study, a significant amount of variation in pre-treatment HR-QoL could be explained by patient's perceptions of their illness and treatment and by the coping strategy used. In particular, patients' *Illness Identity* (the amount of symptoms attributed to their HNC) and beliefs about the likely *Timeline* (perceptions about the length of time the illness would last) explained a significant amount of variance in HR-QoL and Global QoL. Therefore, null hypothesis 2a was rejected.

However, surprisingly, it was found that components of the SRM could not explain any of the variance in individualised QoL. Individualised QoL was only associated with the emotional response to the illness in the form of anxiety levels, therefore, hypothesis 2b was accepted. It may be that individualised measure at baseline was tapping into an overriding anxiety due to the recent diagnosis with cancer.

In addition, coping was related to QoL in the present study. In particular, the use of more adaptive strategies, such as positive reframing, was associated with better QoL, and maladaptive strategies such as substance use and self-blame were associated with a worse QoL. Previous research has highlighted the relationship between the HR-QoL functional domain and coping. For example, Hassanein et al., (2001) found associations between worse functioning as measured by the University of Washington Quality of Life Questionnaire (Hassan et al., 1993) and ineffective coping styles, such as helplessness & hopelessness, anxious preoccupation and fatalism (Hassanein et al., 2001). List et al., (2002) found that maladaptive coping strategies of cognitive escape-avoidance (i.e. sleeping more than usual) and behavioural escape avoidance (not seeking help or waiting before taking action) were related to poorer global QoL (List et al., 2002).

As expected, depression explained a large amount of variance in HR-QoL, which is consistent with previous research (de Graeff et al., 2000b; Hammerlid et al., 2001b). However, it is interesting to note that variance in patient generated QoL was not explained by depressive symptoms. Items included on HR-QoL instruments include depressive symptoms and, therefore, it is not surprising if overlap with the HADS is found. Despite this, the relationship between physical symptoms, depression and QoL is far from understood and it is possible that this relationship is moderated by individual factors such as personality. Further research is needed to unravel these relationships.

In contrast to previous research (Aarstad et al., 2003; Allison et al., 2000), personality was not found to be an important explanatory variable of QoL in this study. This may have been due to the measure used or may have been due to personality exerting an influence indirectly via beliefs. Indeed significant relations were found between optimism and beliefs about the timeline and personal controllability of the illness, indicating that patients with higher levels of dispositional optimism had strong perceptions of personal control and beliefs that their illness

would not last a long time. This is in line with discussions that personality is potentially influential in the formation of cognitive representations (Diefenbach et al., 1996).

Levels of anxiety were reported to be higher than levels of depression prior to treatment, with 47% of the sample scoring within the limits for possible or probable clinical anxiety, but only 20% scoring within the same limits for clinical depression. There was no significant gender difference. Levels of depression in the literature have been shown to vary considerably (see Chapter 2), however, levels in the present sample were found to be similar to pre-treatment levels reported in both cross-sectional and prospective designed studies (D'Antonio et al., 1998; de Graeff et al., 2000b). It is possible, however, as levels have been reported as higher in the literature (Birkhaug et al., 2002; Duffy et al., 2002)that the sample is not representative of all patients with HNC and that patients with higher levels of depression did not take part.

7.4.1 Limitations

The main limitation of this study is its cross-sectional design. This means that no inferences can be made about the causal direction with which variables are exerting an influence on the other. In addition, the models were not stable indicating that they may not be generalisable outside of this data set.

7.4.2 Implications

Despite these limitations, the findings are potentially relevant to clinical practice. Clinicians could gain a better understanding of their patients' views about their illness and treatment, which would promote a better clinician-patient partnership. Our findings suggest that the illness and treatment perceptions approach, as used in this study, could be a useful method for eliciting and understanding patients' particular beliefs regarding HNC and its treatment.

In order to maximise post-treatment QoL and psychological adaptation, simple interventions could therefore address particular beliefs such as treatment concerns and the time scale of the illness, and focus on fostering more adaptive coping strategies such as acceptance and the use of emotional and instrumental support, whilst avoiding maladaptive coping strategies, such as self-blame and substance use. This may be achievable through cognitive-behavioural therapy or patient counselling aimed at altering the negative beliefs about the treatment and course of the illness whilst encouraging a sense of control over the illness. Other methods of coping such as seeking social support and accepting the situation could be offered as alternatives to avoidance coping such as self-blame and using substances such as drugs and alcohol. Friends and family could be involved if acceptable to the patient and practical. Since recent research has indicated that an approach focusing on illness perceptions can be successfully adopted to improve recovery in post- MI patients, (Petrie, Cameron, Ellis, Buick, & Weinman, 2002) this offers a very promising and novel way for improving QoL.

7.4.3 Further research

The patterns that have emerged from these preliminary cross-sectional analyses need to be confirmed longitudinally. Longitudinal data would give more insight into the causal relationship between variables, something that cross-sectional studies do not allow.

7.4.4 Conclusions

The results from these pre-treatment cross-sectional data have shown that key components of the SRM were explanatory factors of outcomes such as HR-QoL, depression and anxiety. Individualised QoL was partially correlated with HR-QoL measures, in particular, emotional and mental health HR-QoL subscales. This outcome measure was not however, found to be associated with any of the components of the SRM.

CHAPTER 8

THE PREDICTIVE FACTORS OF LONGITUDINAL QOL: A REPEAT MEASURES STUDY

8.1 INTRODUCTION

The previous chapter assessing cross-sectional pre-treatment relationships, demonstrated that a number of illness representations and coping strategies were associated with outcomes such as HR-QoL, and depression and anxiety. However, surprisingly it was found that components of the SRM, emotional outcomes aside, could not explain any of the variance in individualised QoL. Individualised QoL was only associated with the emotional response to the illness in the form of anxiety levels.

Although not much is known about how the beliefs of HNC patients relate to longitudinal outcomes such as QoL, research with other illness groups demonstrates that patient beliefs, in particular having a strong illness identity, perceptions of the negative consequences of the illness and chronic timeline beliefs, are related to worse HR-QoL and emotional distress (see chapter 3). The literature also demonstrates that patient beliefs may be more predictive of outcomes than coping mechanisms (chapter 3), and that beliefs and outcomes change over time (chapters 2 and 3). Therefore, a longitudinal study was essential in order to determine whether the relationships between key components of the SRM and outcomes found at baseline were similar to those shown over time. The findings from this longitudinal study could have implications for both the need for longitudinal assessment and for informing the development of interventions to maximise longitudinal outcomes, at an earlier stage.

Furthermore, if components of the SRM were found to be predictive of the extent to which expectations were perceived by patients to be fulfilled after treatment, then this could also have implications for the targeting of interventions. Realistic goal setting is related to adequate

information regarding the risks, benefits, alternatives and outcomes of treatment especially in terms of expected functional ability (Calman, 1984b), therefore, any common areas pinpointed to be worse than expected could be focused on for future information provision and increased attention.

8.2 RESEARCH QUESTIONS

Four main objectives or research questions were proposed for this chapter:

1) To what extent are components of the SRM predictive of longitudinal outcomes?

2) What factors are predictive of fulfilment of expectations after treatment?

3) Is there any evidence for response shift occurring between baseline and follow-up at T3? For example, does reprioritisation (of QoL domains) occur between diagnosis and 6-8 months after treatment? Is reprioritisation associated with improvement in QoL over time?

4) To what extent are baseline factors predictive of drop-out at T3?

8.3 HYPOTHESES

The following null hypotheses were tested in this chapter:

1) Illness and treatment perceptions assessed at baseline will not explain a significant amount of variance in longitudinal outcomes of:

a) Standardised HR-QoL,

b) Individualised QoL

c) Depression

d) Anxiety

2) Fulfilment of expectations after treatment will not be predicted by illness or treatment perceptions assessed at baseline.

3) There will be no evidence for response-shift occurring between baseline and follow-up as measured by reprioritisation of QoL.

4) There will be no difference in baseline characteristics (socio-demographic and treatment related, or psychological factors) between patients who drop out of the study at T3 and those that do not.

8.4 METHODS

8.4.1 Design

This chapter describes analyses using data from the prospective questionnaire based study at all time points. Longitudinal analysis focuses on baseline (T1) and 6-8 month follow-up (T3) data. (For further details see chapters 6 and 7).

8.4.2 Procedure

Procedural details can be found in chapter 5 part 1.

8.4.3 Measures

8.4.3.1 Outcome measures

HR-QoL and individualised QoL:

- **EORTC QLQ-C30** (Aaronson et al., 1993).
- **SF-12v2** (Ware et al., 2002).
- **Patient Generated Index** (Ruta et al., 1994).

Emotional outcomes:

- **HADS** (Zigmond et al., 1983) to measure state depression and anxiety.

8.4.3.2 Predictive factors:

- **IPQ-R** (Moss-Morris et al., 2002) to elicit illness representations.
- **BMQ-Specific** (Horne et al., 1999) subscales of Necessity and Concerns to measure treatment representations.
- **Brief COPE** (Carver, 1997) to examine coping strategies.

- **LOT-R** (Scheier et al., 1994) to measure personality in the form of life orientation (dispositional optimism).
- **SCIP** (see chapter 5 part 2) to measure satisfaction with information.
- **Expectations** ratings (see chapter 5 part 1), to assess the extent to which patients expectations had been met post-treatment.

Full descriptions of these measures can be found in chapter 5, methodology part 1.

Socio-demographic variables of: age, gender, socio-economic status, marital status and ethnicity were assessed as described in the methods section (chapter 5). Clinical factors such as site and stage of cancer, and treatment planning were also assessed as described in chapter 5.

8.4.4 Participants

A sample of eighty-two newly diagnosed HNC patients were recruited into the study prior to treatment (T1) as described previously in chapters 6 and 7. One month after treatment had finished (T2), sixty-eight patients (83% retention rate) completed the first follow-up questionnaire. Six to eight months after treatment (T3), fifty patients completed the last follow-up questionnaire (61% retention rate). The socio-demographic and clinical characteristics of follow-up samples are described in this chapter.

8.4.5 Statistical analysis

Preliminary analysis

To test for differences between measures at baseline and at follow-up assessments, within subjects ANOVAs (for repeat measures) were conducted, with plots of the mean values at each time point. Boxplots were obtained to check for extreme cases and any present were removed prior to ANOVA testing. Mauchly's test of sphericity between scores were conducted to test for homogeneity of covariance (Mauchly's test should be insignificant for sphericity to be

assumed).Where significant differences were shown, paired-sample t-tests were then conducted to further investigate the differences. Kruskall-Wallis tests were used for non-parametric data.

For clarity, further analyses have been divided into four sections relating to each research question.

8.4.5.1 Methods of analysis to investigate predictors of long-term QoL

To test the associations between explanatory variables measured at baseline (T1) and longitudinal outcomes assessed 6-8 months post-treatment (T3), cross-lag correlations were conducted. In order to assess a range of outcomes encompassing: HR-QoL, individualised QoL and emotional outcomes, six outcome variables were used throughout these analyses. The EORTC QLQ-C30 global QoL score, SF-12: PCS and MCS scores were used as markers of HR-QoL, PGI scores for individualised QoL, and depression and anxiety scores for markers of emotional outcomes.

Multiple regression analyses using the stepwise method for variable entry were conducted for each outcome variable, entering factors found to be significantly associated with outcome from the cross-lag correlations. Entry of variables and diagnostics were performed as described previously.

8.4.5.2 Analysis to determine whether factors are predictive of fulfilment of expectations after treatment

The three items assessing the extent of fulfilment of expectations 6-8 months after treatment were used in this analysis. Items assessing the fulfilment of expectations regarding the outcome of treatment and the extent of recovery were dichotomised into groups reporting their experiences to be 'worse than expected' (scored 0) and 'better' or the 'same as expected' (scored 1). Data from patients reporting 'no expectations' were not used in this analysis. The

item assessing expectations regarding the overall treatment and recovery period to date was used as an ordinal outcome measure scored 0 to 3. Point biserial cross-lag correlations were conducted between expectations one and two and baseline predictive factors. Any factors found to be significantly correlated were entered into regression models. A backward conditional method was used for variable entry into the logistic regression for the reasons outlined in chapter 6.

Linear regression was conducted in order to assess which of the pre-treatment factors associated with the extent to which overall expectations were met, using cross-lag correlations, remained predictive when entered into a model together. Variables were entered in the regression analyses at $p<0.05$ and removed from the model at $p>0.10$. Residual diagnostics from each of the models were examined in order to determine the degree to which the models fitted the data.

8.4.5.3 Analysis to determine response-shift in the data: Reprioritisation over time

To determine whether reprioritisation had occurred in individualised QoL domains between T1 and T3, the first and thus most important domain reported to be affected at T3 was compared with the highest priority baseline domain. Patients were given a '+' if their most important area of their life affected by their HNC changed after treatment and given a '-' if it had remained the same throughout the period. In order to explore whether reprioritisation was associated with either an improvement or worse QoL over time, Spearman's rank correlations were conducted. QoL scores were derived by subtracting PGI scores at T1 from scores at T3 and dichotomising the resulting scores into either: 0='decline in QoL over time' or 1='improvement in QoL over time'.

8.4.5.4 Analysis of the differences between full responders versus drop-outs at T3

In order to ascertain whether patients who did not complete the whole study could be predicted from baseline psychological characteristics or variance in QoL, Mann-Whitney U tests for two independent samples were conducted. Psychological factors of: illness and treatment perceptions, depression, anxiety, coping mechanisms and satisfaction with information, and QoL indices of: PGI scores, global QoL (EORTC QLQ-C30), PCS & MCS (SF-12) were entered with the grouping variable of whether respondents were fully concordant or not. Level of painkiller use was also included in the unlikely event that pain was not tapped into by any of the other measures.

In order to investigate what proportion of study compliance could be predicted from baseline characteristics, logistic regression analysis was conducted. Any socio-demographic or medical/treatment related factors found to significantly differ between the two groups were entered first into the regression, these were then followed by any significantly different psychological factors or outcomes variables also assessed at baseline. Full responders were coded 0 and drop-outs were coded 1. A backward conditional method was again used for variable entry into the logistic regression.

8.5 RESULTS

Sample characteristics

A breakdown of the samples in relation to the original recruited sample can be seen in Table 8.1. At first follow-up, sixty-eight patients responded giving an 83% response rate. At second follow-up, fifty patients responded giving a 61% response rate.

In total, 6% of patients died during the study, 17% had recurrences, 2% entered palliative care, and one patient had severe complications after surgery and took many months to heal before undergoing radiotherapy. This left insufficient time to collect follow-up data.

The reasons for non-compliance in 12% of the sample are known only for a few patients. One patient refused further treatment and did not want to continue with the study, and another patient was currently experiencing flashbacks from severe post traumatic stress disorder, due to a previous road traffic accident and would not continue with the questions. Similarly, another patient was too distressed to continue in the study. Two patients were found to have moved without leaving a forwarding address with the hospital.

Table 8.1: Breakdown of sample of respondents at each time point

Breakdown of original sample (n=82)	Reason (if known)	n	%
Full data set	-	**50**	**61%**
T2 data missing		**14**	**17%**
	Recurrence after T1	3	4%
	Death after T1	3	4%
	Entered palliative care after T1	1	1%
	Severe complications after T1 –allowing insufficient time for follow-up	1	1%
	Moved without address	2	2%
	Non-compliant	4	5%
T3 data missing	(as above +)	**32**	**39%**
	Recurrence after T2	11	13%
	Death after T2	2	2%
	Metastasis of disease – entered palliative care	1	1%
	Non-compliant	4	5%

Table 8.2: Socio-demographic and clinical characteristics of follow-up samples and statistical analysis comparing patient samples at follow-up with sample at baseline

Characteristic	Follow-up sample at T2 (n=68) n (%)	Test statistic†	Follow-up sample at T3 (n=50) n (%)	Test statistic†
Gender				
Male	44 (65)	χ^2=0.23;p=0.63	29 (58)	χ^2=3.51;p=0.06
Female	24 (35)		21 (42)	
Age (yrs)				
Mean (SD)	59.6 (13.10)	t(80)=2.74;p=0.65	60.94 (12.67)	t(80)=1.17;p=0.34
Range	23-89			
Ethnicity				
White	62 (91)	Cramér's V=0.02; p=0.84	47 (94)	Cramér's V=0.11; p=0.30
Other	6 (9)		3 (6)	
Marital Status				
Single/ widowed/divorced	28 (41)	Cramér's V=0.10; p=0.38	22 (44)	Cramér's V=0.13; p=0.25
Married /cohabiting	40 (59)		28 (56)	
Highest Qualification*				
None	21 (31)	Cramér's V=0.17; p=0.88	15 (30)	Cramér's V=0.31; p=0.30
GCSE/O' level	2 (18)		8 (16)	
GCE/A' level	8 (12)		4 (8)	
Higher education	9 (13)		9 (18)	
Degree or higher	14 (21)		11 (22)	
AJCC Stage of cancer*				
Stage 1	19 (28)	Cramér's V=0.48; p=0.003	17 (34)	Cramér's V=0.53; p=0.001
Stage 2	16 (24)		11 (22)	
Stage 3	12 (18)		10 (20)	
Stage 4a,b & c	16 (24)		7 (14)	
Stage dichotomised*				
Early stage (1 & 2)	35 (52)	Cramér's V=0.21; p=0.07	28 (56)	Cramér's V=0.27; p=0.02
Advanced stage (3&4)	28 (41)		17 (34)	

Characteristic	Follow-up sample at T2 (n=68) n	(%)	Test statistic†	Follow-up sample at T3 (n=50) n	(%)	Test statistic†
Treatment						
Surgery only (S)	20	(29)	Cramér's V=0.26; p=0.26	18	(36)	Cramér's V=0.36; p=0.03
Radiotherapy only (RT)	17	(25)		14	(28)	
S & RT	21	(31)		12	(24)	
RT & Chemotherapy (CT)	6	(9)		4	(8)	
S & RT & CT	4	(6)		2	(4)	
Site of cancer (ICD-10 code)						
Lip (C00)	3	(4)		3	(6)	
Tongue (C01&2)	17	(25)		12	(24)	
Floor of mouth (C04)	12	(18)		7	(14)	
Palate (C05)	2	(3)		2	(4)	
Other& unspecified parts of mouth (C06)	4	(6)	Cramér's V=0.39; p=0.34	4	(8)	Cramér's V=0.33; p=0.61
Parotid/salivary gland (C07&8)	2	(3)		1	(2)	
Tonsil (C09)	5	(7)		4	(8)	
Oropharynx (C10)	7	(10)		5	(10)	
Hypopharynx (C13)	1	(2)		1	(2)	
Laryngeal/glottic (C32)	14	(21)		10	(20)	
Skin (non-melanoma) (C44)	1	(2)		1	(2)	

* data missing/unobtainable

† Independent t-tests, Chi² tests and Cramér's V tests comparing respondents at each time point with drop-outs from original baseline sample

Table 8.2 shows the socio-demographic and clinical characteristics of the follow-up samples. There were no significant differences between the sample of patients at T2 and those that dropped out, excluding stage of cancer, which was found to be higher in patients that were not included in T2 assessment. At longitudinal follow-up, stage was found to be significantly lower in the patients included in assessment (T3); in addition patients were significantly less likely to have combined therapy than those who were not included.

Preliminary analysis

Tables 8.3 to 8.7 present the means (SD), medians, ranges and Cronbach's Alpha's for measures completed at T2 and T3 follow-up.

Individualised QoL

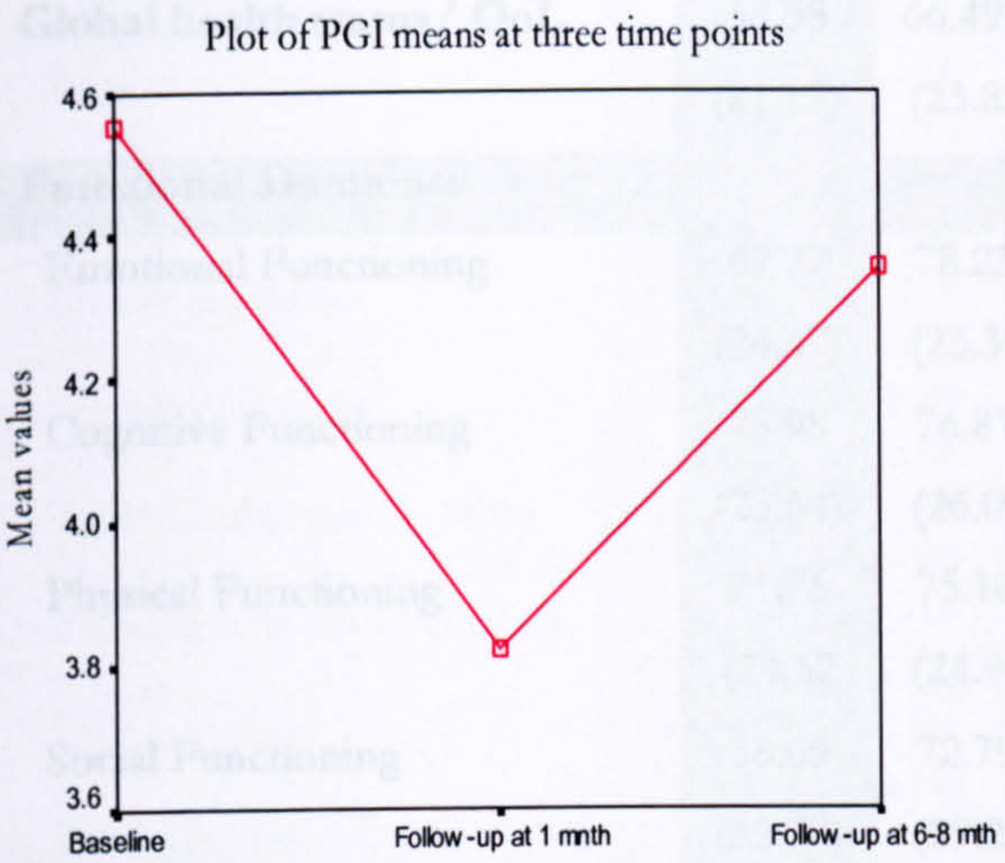
No significant differences between PGI scores at baseline (see Table 7.2) and follow-up one month post-treatment and 6-8 months after treatment were found ($F(2,62)=2.33;p>0.05$). Plots displaying changes in scores over time (figure 8.1), indicate that individualised QoL decreased shortly after treatment. Scores on the PGI could range from 0 to 10, therefore mean values at both time points indicate that individualised QoL was slightly negatively skewed and thus perceived to be fairly low (Table 8.3).

Table 8.3: Mean (SD), median and range for individualised QoL at 1 month (n=54) and 6-8 months (n=40) post-treatment

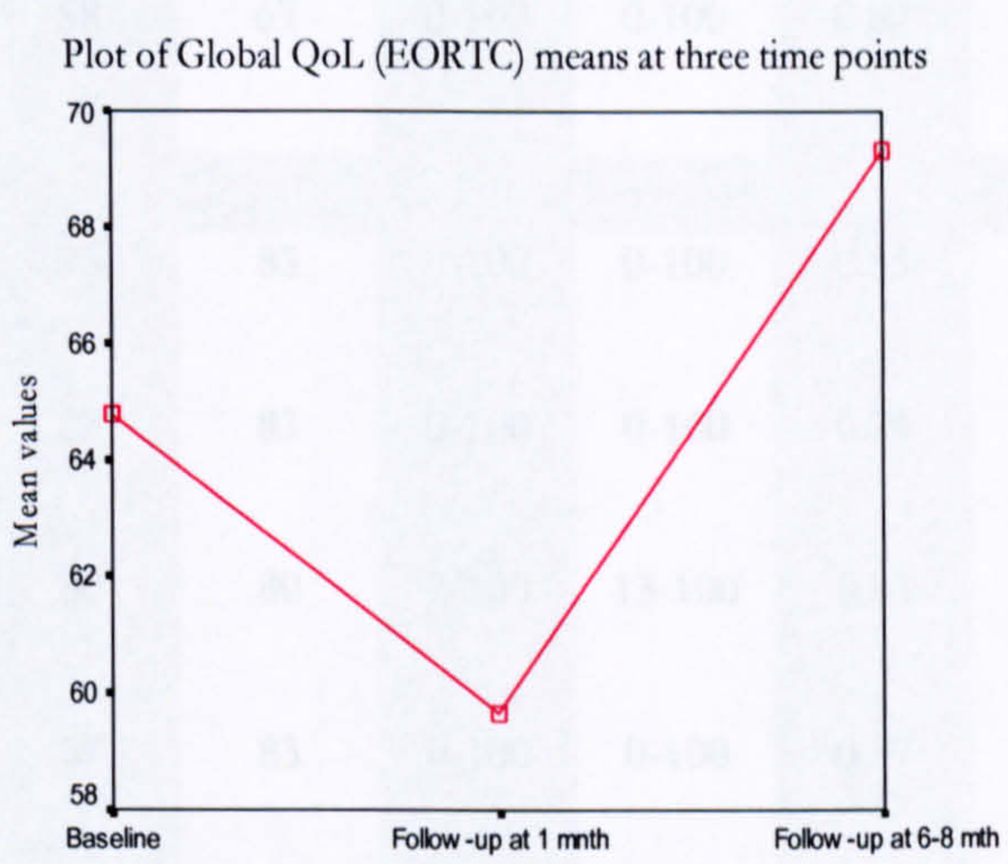
Individualised QoL	**Mean (SD)**		**Median**		**Range**	
	1 mnth	**6-8 mnths**	**1 mnth**	**6-8 mnths**	**1 mnth**	**6-8 mnths**
Patient Generated Index	3.39 (1.77)	4.34 (2.22)	3.29	4.39	0-8.7	0.6-10

Cronbach's alpha cannot be computed as overall QoL only consists of 1 final score.

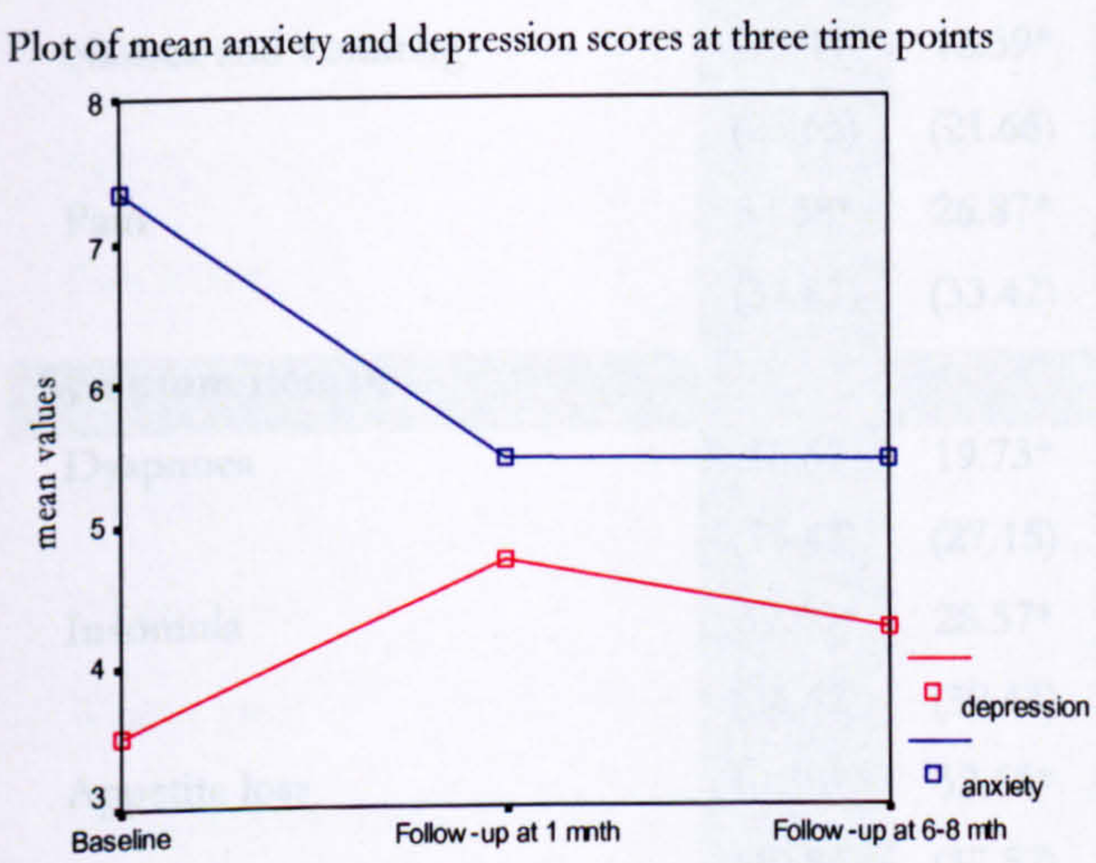
Figure 8.1: Plots of mean scores[8] of main outcome variables to show change over time



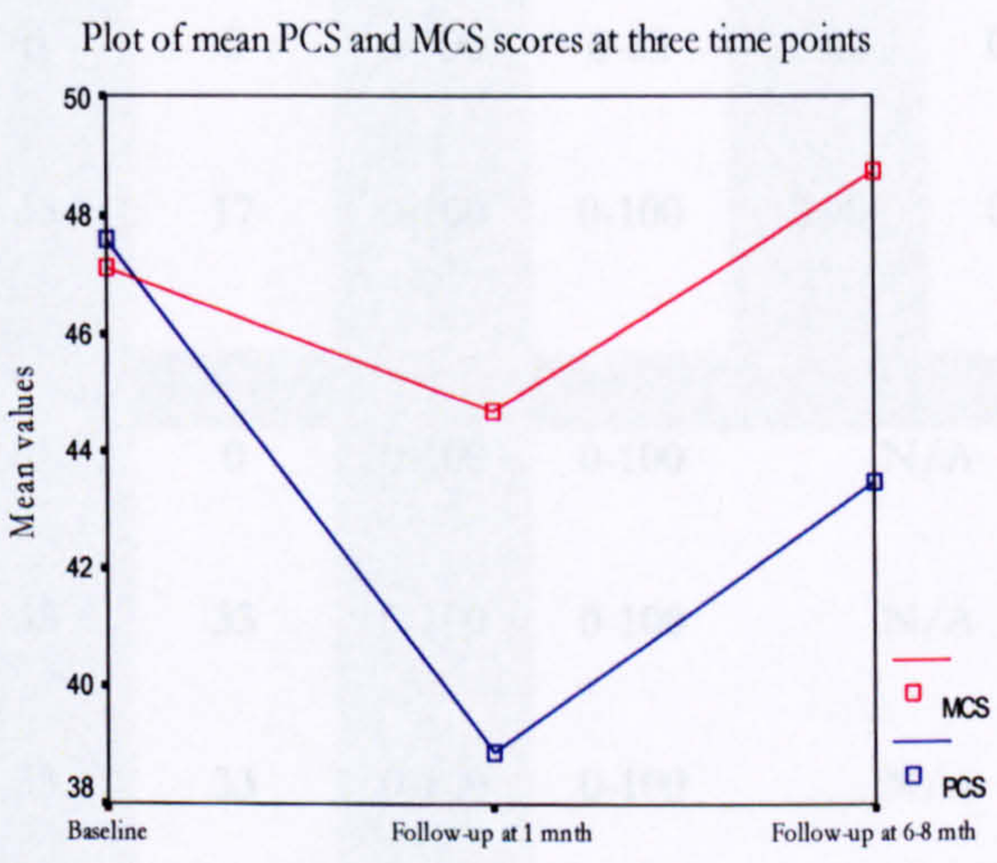
Individualised QoL



GLOBAL health status/ QoL



HADS scores



SF12v2 Component Summary scores

[8] The mean values displayed in these plots are not the same as those presented in the tables of chapters 7 and 8, as only data from patients with full data sets are included in the ANOVAs and plots.

Table 8.4: Means (SD), medians, range and Cronbach's alpha values for cancer specific HR-QoL at 1 month (n=68) and 6-8 months (n=50) post-treatment

EORTC QLQ-C30 Domain	Mean (SD)		Median		Range		Cronbach's α	
	1 mnth	6-8 mnths	1 mnth	6-8 mnths	1 mnth	6-8 mnths	1 mnth	6-8 mnths
Global health status/ QoL	58.58 (21.17)	66.49** (23.85)	58	67	0-100	0-100	0.82	0.94
Functional Domains:								
Emotional Functioning	67.77 (24.47)	78.23* (25.39)	75	83	0-100	0-100	0.85	0.88
Cognitive Functioning	75.98 (23.64)	76.87* (26.09)	83	83	0-100	0-100	0.74	0.79
Physical Functioning	71.76 (24.52	75.10* (24.94)	80	80	7-100	13-100	0.85	0.88
Social Functioning	58.09 (32.77)	72.79* (29.20)	67	83	0-100	0-100	0.87	0.82
Role Functioning	55.47* (32.75)	71.77* (33.37)	50	83	0-100	0-100	0.82	0.93
Symptom Scales:								
Fatigue	43.45* (28.74)	34.49** (31.20)	44	33	0-100	0-100	0.89	0.94
Nausea and vomiting	15.44 (25.65)	12.59* (21.66)	0	0	0-100	0-83	0.86	0.76
Pain	34.58* (31.82)	26.87* (33.47)	33	17	0-100	0-100	0.90	0.85
Symptom items‡:								
Dyspnoea	16.67 (25.43)	19.73* (27.15)	0	0	0-100	0-100	N/A	
Insomnia	39.90* (36.62)	28.57* (30.43)	33	33	0-100	0-100	N/A	
Appetite loss	40.30** (40.84)	32.65* (37.57)	33	33	0-100	0-100	N/A	
Constipation	32.34** (34.80)	21.09* (26.95)	33	0	0-100	0-100	N/A	
Diarrhoea	10.45** (24.07)	14.97* (27.27)	0	0	0-100	0-100	N/A	
Financial Difficulties	28.86** (37.11)	19.73* (34.64)	0	0	0-100	0-100	N/A	

* data from 1 participant missing
** data from 2 participants missing
‡ Cronbach's alpha cannot be computed as symptom items consist of 1 item only.

Table 8.5: Means (SD), medians, range and Cronbach's alpha values for head and neck cancer specific HR-QoL at 1 month (n=68) and 6-8 months (n=50) post-treatment

EORTC QLQ-H&N35 Domain	Mean (SD)		Median		Min – max score		Cronbach's α	
	1 mnth	6-8 mnths	1 mnth	6-8 mnths	1 mnth	6-8 mnths	1 mnth	6-8 mnths
Symptom Scales[9]:								
Pain	37.63* (27.63)	26.19* (31.04)	33	8	0-100	0-100	0.84	0.92
Swallowing	30.51* (30.23)	15.96** (21.13)	24	8	0-100	0-83	0.90	0.82
Senses problems	37.37* (33.60)	16.33* (25.80)	33	0	0-100	0-100	0.74	0.76
Speech problems	30.73* (26.69)	23.84** (23.03)	22	22	0-100	0-89	0.75	0.68
Trouble with social eating	40.76* (31.71)	30.78* (33.43)	33	17	0-100	0-100	0.88	0.93
Trouble with social contact	18.87* (23.38)	13.74* (20.34)	13	7	0-100	0-80	0.88	0.83
Less sexuality	40.68† (39.42)	26.25† (35.38)	33	0	0-100	0-100	0.93	0.98
Symptom items‡								
Teeth	26.26* (33.34)	18.75** (32.18)	0	0	0-100	0-100	N/A	
Opening mouth	45.45* (40.36)	26.53* (35.99)	33	0	0-100	0-100	N/A	
Dry mouth	45.45* (38.18)	40.82* (35.53)	33	33	0-100	0-100	N/A	
Sticky saliva	49.49* (41.45)	33.33** (36.39)	33	33	0-100	0-100	N/A	
Coughing	30.30* (32.41)	23.13* (28.22)	33	0	0-100	0-100	N/A	
Felt ill	23.74* (31.36)	15.65* (27.30)	0	0	0-100	0-100	N/A	
Pain killers	63.08* (48.64)	36.73* (48.71	100	0	0-100	0-100	N/A	
Nutritional supplements	64.62* (48.19)	42.86* (50.00)	100	0	0-100	1-100	N/A	
Feeding tube	24.62* (43.41)	10.20* (30.58)	0	0	0-100	0-100	N/A	
Weight loss	50.77* (50.38)	26.53* (44.61)	100	0	0-100	0-100	N/A	
Weight gain	29.23* (45.84)	28.57* (45.64)	0	0	0-100	0-100	N/A	
Shoulder function$	28.79* (29.50)	22.96* (27.40)	25	0	0-75	0-75	N/A	

‡ Cronbach's alpha cannot be computed as symptom items consist of 1 item only.
* Data from 1 participant missing
** Data from 2-3 participants missing
$ Extra item added to questionnaire (see methods chapter)
† Data from 10 participants missing or reported n/a at each time point.

[9] High scores for symptom scales or symptom items represent high levels of symptoms/problems, unlike functional scales and overall QoL, whereby higher scores represent higher levels of functioning.

HR-QoL

Global health status/ QoL as measured by the EORTC QLQ-C30 was found to diminish between baseline (see Table 7.3) and one month after treatment (Table 8.4), however at 6-8 months post treatment, ratings of global QoL had exceeded baseline levels (Figure 8.1). Neither of these ratings proved significantly different to baseline levels. However, significant differences were detected between follow-up at 1 month and 6-8 months after treatment ($t(43)=16.24; p<0.001$).

The results shown in Table 8.4 indicate that mean scores for Emotional and Cognitive Functioning domains increased steadily from baseline to longitudinal follow-up. However, scores on the Physical, Social, and Role Functioning domains diminished at one month follow-up and did not reach baseline scores at longitudinal assessment.

Scores on the general cancer symptom scales and symptom items (Table 8.4) indicated that symptoms peaked at the first follow-up after treatment then reduced after 6-8 months, as expected. Symptoms specific to the head and neck region remained high at both time points but similar to generalised symptoms peaked at first follow-up (Table 8.5). Scores on domains such as 'trouble with social eating', 'dry mouth' and 'sticky saliva' remained high even after 6-8 months post-treatment. Shoulder function remained impaired even at 6-8 months post treatment. Many of the problems seen at 6-8 months may reflect permanently impaired domains as a result of treatment. Despite these findings, perceptions of feeling ill diminished below baseline levels and the use of pain-killers dramatically reduced to half the score of that at baseline. Unfortunately, these improvements probably reflected the fact that responders in the longitudinal follow-up sample were less impaired and had lower stages of cancer at diagnosis than patients who had dropped out.

Scores for generalised HR-QoL (SF-12) showed similar trends (Table 8.6). Domains of: Role Emotional, Role Physical and Bodily Pain remained similar to baseline levels (see Table 7.5) 6-8 months after treatment demonstrating a reduction shortly after treatment. The Mental Health domain demonstrated a slight improvement after 6-8 months from baseline levels. However, domains of Social Functioning and Physical Functioning showed severe levels of decline and impairment even after 6-8 months post treatment. Levels of vitality were low at baseline (mean=50; SD=27.5) and demonstrated a decrease even at 6-8 months.

Table 8.6: Means (SD), medians, ranges and Cronbach's Alpha values for generalised HR-QoL at 1 month (n=68) and 6-8 months (n=50) post-treatment

SF-12v2 Domain	Mean (SD)		Median		Min - max		Cronbach's α	
	1 mnth	6-8 mnths	1 mnth	6-8 mnths	1 mnth	6-8 mnths	1 mnth	6-8 mnths
Mental Health	61.95 (23.20)	68.75 (22.34)	63	75	0-100	12.5-100	0.75	0.78
Role Emotional	63.62 (31.74)	73.47* (25.08)	75	75	0-100	25-100	0.93	0.88
Social Functioning‡	55.88 (33.77)	47.45* (28.06)	50	50	0-100	0-75	N/A	
Role Physical	43.47 (29.54)	66.07* (30.83)	50	75	0-100	0-100	0.92	0.93
General Health‡	44.25 (29.60)	55.00 (29.80)	25	60	0-100	0-100	N/A	
Bodily Pain‡	61.57 (32.95)	73.5 (33.28)	75	100	0-100	0-100	N/A	
Vitality‡	33.46 (26.49)	44.5 (26.86)	25	50	0-75	0-100	N/A	
Physical Functioning	58.21 (35.46)	56.63* (34.53)	75	50	0-100	0-100	0.74	0.66
Mental Component Summary (MCS)	42.84 (11.04)	49.00 (8.33)	45	50	14-62	32-66	N/A	
Physical Component Summary (PCS)	38.88 (10.13)	42.92 (11.84)	41	45	19-56	14-60	N/A	

* data from 1 participant missing
‡ Cronbach's alpha cannot be computed as domains only consist of 1 item.

MCS and PCS scores remained poorer 6-8 months after treatment than the normal population (US derived and not age or sex adjusted), however, it is interesting to note from the plot of mean PCS and MCS scores at three time points (Figure 8.1) that although both summary scores showed the same pattern of decline and increase, Physical Component Summary scores remained severely impaired with a mean of 43, whereas Mental

Component Summary scores rose above levels shown at baseline to approaching average. Multivariate analyses demonstrated that there were significant differences between both PCS and MCS scores over time ($F(2,92)=24.45;p=0.001$, and $F(2,90)=3.66;p=0.03$, respectively). T-tests revealed that there were significant differences between baseline and T2 follow-up scores on PCS scores ($t(64)=7.92;p<0.001$), and baseline and T3 follow-up scores ($t(47)=4.1;p<0.001$). There were no significant differences between MCS scores at baseline and either T2 or T3 scores ($p>0.05$). However, there was a significant improvement in scores between T2 and T3 ($t(46)=-2.99;p=0.005$).

Anxiety and depression

Anxiety scores remained higher than depression scores at all three time points (Table 8.7). However the patterns of scores are markedly different. From Figure 8.1 it can be seen that anxiety levels were high following diagnosis but quickly diminished after treatment, remaining stable over time. Levels of depression, however, were relatively low at baseline (see table 7.7), peaking just after treatment then subsequently reducing over time. Levels throughout this period remain low. Analyses revealed significant differences between anxiety and depression scores over time ($F(2,92)=7.22;p=0.001$, and $F(2,92)=3.2;p=0.05$, respectively). Significant differences were shown between baseline anxiety and depression scores and each time-point. Both scales showed good levels of internal consistency.

Table 8.7: Means (SD), medians, ranges and Cronbach's Alpha values for 1 month (n=68) and 6-8 month (n=50) post-treatment depression and anxiety scores

Anxiety & Depression	**Mean (SD)**		**Median**		**Min – max score**		**Cronbach's α**	
HADS subscale:	**1 mnth**	**6-8 mnths**	**1 mnth**	**6-8 mnths**	**1 mnth**	**6-8 mnths**	**1 mnth**	**6-8 mnths**
Anxiety	6.51** (4.90)	5.62 (4.55)	6.0	5.0	0-18	0-20	0.91	0.89
Depression	5.74** (4.07)	4.68 (4.45)	5.0	3.0	0-18	0-19	0.85	0.89

** data missing for 2 participants

Table 8.8: Means (SD), medians, ranges and Cronbach's Alpha values for 1 month (n=68) and 6-8 month (n=50) post-treatment illness representations, treatment beliefs and coping strategies.

	Mean (SD)		Median		Min – max score		Cronbach's α	
Psychological Factor	**1 mnth**	**6-8 mnths**	**1 mnth**	**6-8 mnths**	**1 mnth**	**6-8 mnths**	**1 mnth**	**6-8 mnths**
BIPQ subscale[10]:								
Illness Identity	3.60 (2.77)	3.30 (2.93)	3.0	3.0	0-10	0-10	N/A	N/A
Timeline	4.35 (2.98)	4.52 (3.62)	4.0	4.0	0-10	0-10	N/A	N/A
Consequences	5.53 (2.91)	4.04 (2.90)	6.0	3.5	0-10	0-10	N/A	N/A
Personal Control	4.45 (3.08)	4.82 (3.42)	5.0	5.0	0-10	0-10	N/A	N/A
Treatment Control	8.57 (2.15)	8.90 (1.58)	9.5	10.0	0-10	5-10	N/A	N/A
Illness Coherence	7.13 (2.82)	7.36 (2.33)	8.0	8.0	0-10	1-10	N/A	N/A
Emotional representations:	4.90 (3.16)	3.92 (3.00)	5.0	3.5	0-10	0-10	N/A	N/A
Emotional response								
Concerns	5.91 (3.37)	4.36 (2.93)	6.0	4.0	0-10	0-10	N/A	N/A
BMQ-Specific subscale[3]:								
Necessity	8.88 (1.47)	8.96 (1.32)	9.5	10	2-10	6-10	0.53	0.77
Concerns	6.79 (2.06)	5.96* (2.35)	7.0	6.0	2-10	2-10	0.64	0.66
Brief COPE subscale†:								
Self Distraction	4.06 (1.70)	3.76 (1.90)	4.0	3.0	2-8	2-8	0.61	0.59
Active Coping	4.70 (1.92)	4.36 (1.88)	5.0	4.0	2-8	2-8	0.75	0.59
Denial	3.43 (1.82)	2.56 (1.03)	3.0	2.0	2-8	2-6	0.73	0.34
Substance Use	3.00 (1.85)	2.94 (1.80)	2.0	2.0	2-8	2-8	0.97	0.98
Use of Emotional Support	4.94 (1.97)	4.14 (1.82)	4.0	4.0	2-8	2-8	0.79	0.81
Use of Instrumental Support	3.95 (1.68)	3.58 (2.13)	4.0	3.0	2-8	2-8	0.76	0.81
Behavioural Disengagement	2.75 (1.36)	2.46 (1.09)	2.0	2.0	2-8	2-6	0.64	0.74
Venting	3.38 (1.40)	3.04 (1.23)	3.0	2.5	2-7	2-6	0.48	0.23
Positive Reframing	4.08 (1.68)	3.76 (1.88)	4.0	3.0	2-8	2-8	0.52	0.70
Planning	4.16 (1.72)	3.72 (1.85)	4.0	3.0	2-8	2-8	0.65	0.65
Humour	4.02 (2.08)	4.42 (2.31)	4.0	4.0	2-8	2-8	0.89	0.91
Acceptance	6.05 (1.99)	6.86 (1.69)	7.0	8.0	2-8	2-8	0.78	0.74
Religion	3.39 (2.04)	3.32 (2.09)	2.0	2.0	2-8	2-8	0.92	0.97
Self-Blame	3.36 (1.8)	3.28 (1.71)	3.0	2.0	2-8	2-8	0.78	0.71

* data missing for 1 participant, † Data missing for between 2 and 4 participants at Time 1 and 0 for Time 2.
N/A= Cronbach's alpha can not be computed as scale only consists of 1 item.

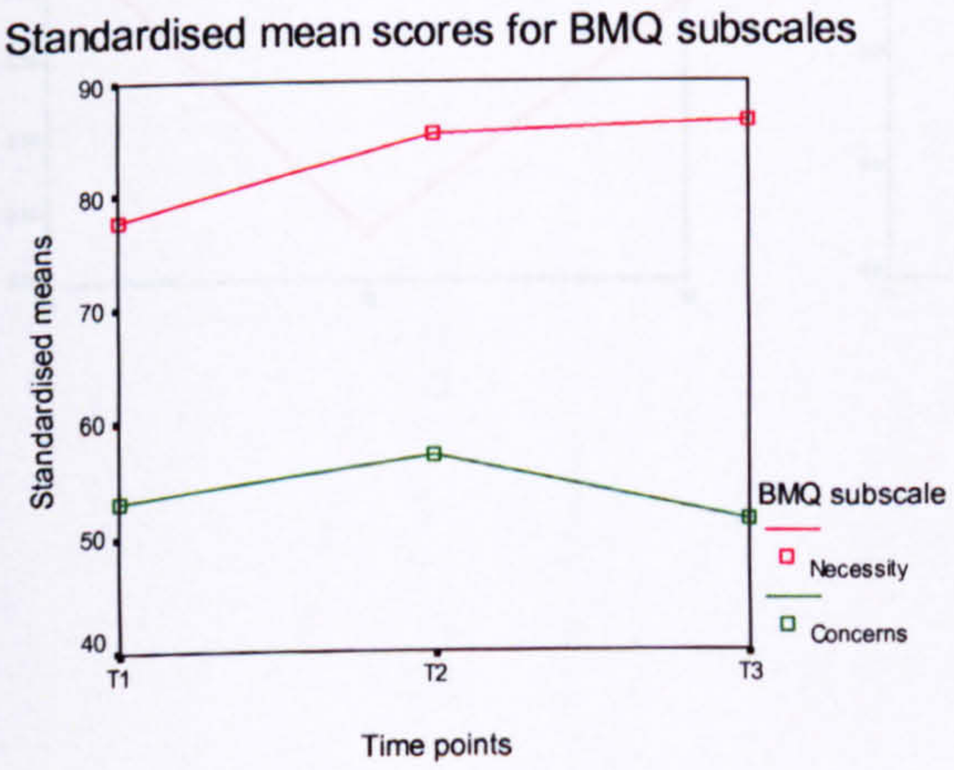
[10] The range of follow-up scores for both the BIPQ subscales and BMQ subscales are different from those at baseline due to differences in items used at follow-up assessment (see chapter 5, Part 1).

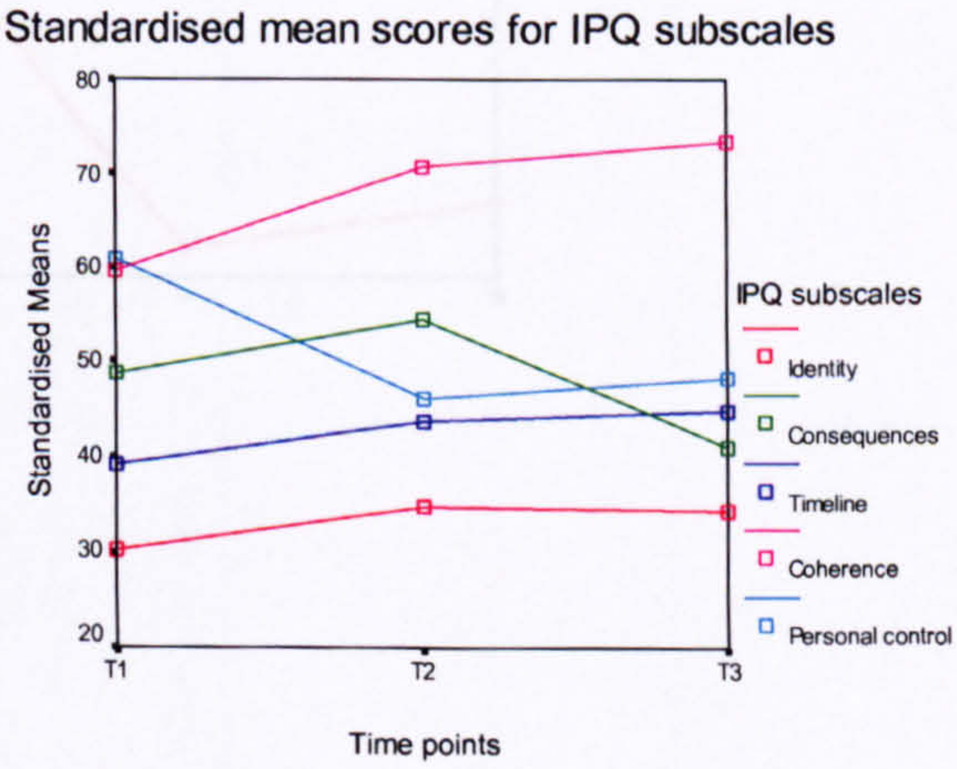
Psychological factors

In order to compare pre- and post treatment illness and treatment beliefs, all scales were standardised on a range from 0 to 100. Tests revealed that there were no significant differences over time in individuals' level of concern about the treatment ($F(2,92)=1.16$; $p>0.05$); illness identity ($F(2,92)=0.67$; $p>0.05$) and timeline beliefs ($F(2,94)=1.12$; $p>0.05$). However, significant differences over time were found regarding beliefs about the necessity of treatment ($F(2,94)=8.33$; $p<0.001$); perceptions about the personal controllability of the illness ($F(2,96)=4.84$; $p<0.01$); the consequences of the illness ($F(2,96)=6.73$; $p<0.005$) and levels of coherence ($F(2,94)=6.70$; $p<0.005$).

Beliefs about the necessity of treatment became significantly stronger between baseline and first assessment (T1) ($t(66)=-2.79$;$p<0.01$), whereas perceptions about the personal controllability of the disease significantly decreased between baseline and T1 assessment ($t(66)=3.80$;$p<0.001$). Perceptions of the negative consequences of the illness increased between baseline and first assessment, however, post-treatment beliefs significantly decreased over time ($t(48)=4.28$;$p<0.001$). Patients' overall understanding and perceptions of coherence regarding the illness increased steadily from baseline to longitudinal assessment (Figure 8.2).

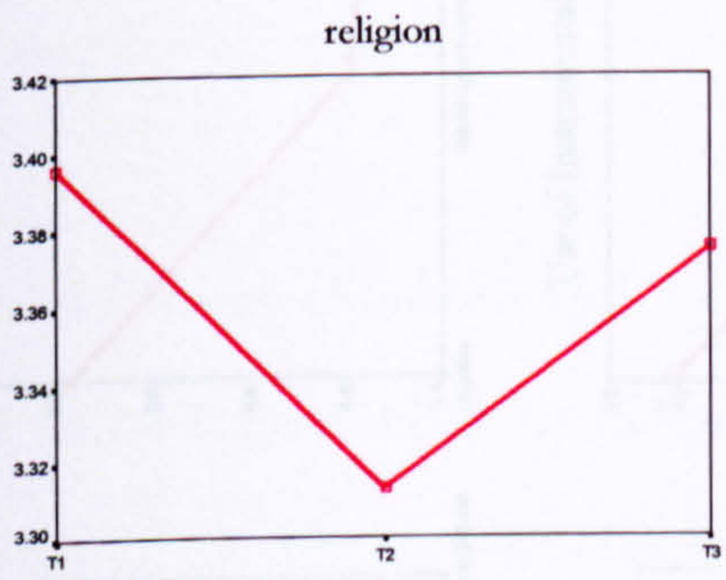
Figure 8.2 Plots of standardised mean scores for BMQ and IPQ subscales over time





The majority of the coping strategies were used at the time of diagnosis with subsequent reductions in their use over time (Figure 8.3). For example, the use of self-distraction, denial and use of emotional and instrumental support and planning techniques were highest after diagnosis and lowest 6-8 months after treatment. Interestingly, positive reframing also showed this trend. The reporting of substance use was highest at diagnosis and lowest shortly after treatment for obvious reasons; however, an increase was evidenced at 6-8 months (Figure 8.3). Behavioural disengagement and venting were at their highest just after treatment. The use of religion showed lowest levels at 1 month after treatment, however similar to acceptance and use of humour, demonstrated a sharp increase 6-8 months post-treatment. Active coping ($z=-2.32;p<0.05$), denial ($z=-3.83;p<0.001$), use of emotional support ($z=-3.78;p<0.001$), use of instrumental support ($z=-2.05;p<0.04$), planning ($z=-2.78;p<0.005$) and self-blame ($z=-2.09;p<0.05$) were all used significantly less 6-8 months after treatment than at baseline. Cronbach's alphas were within an acceptable range for all coping scales, aside from scales of venting and denial. Thus the findings for these two scales should be treated with caution.

Figure 8.3: Plots of mean scores for coping strategies used over time



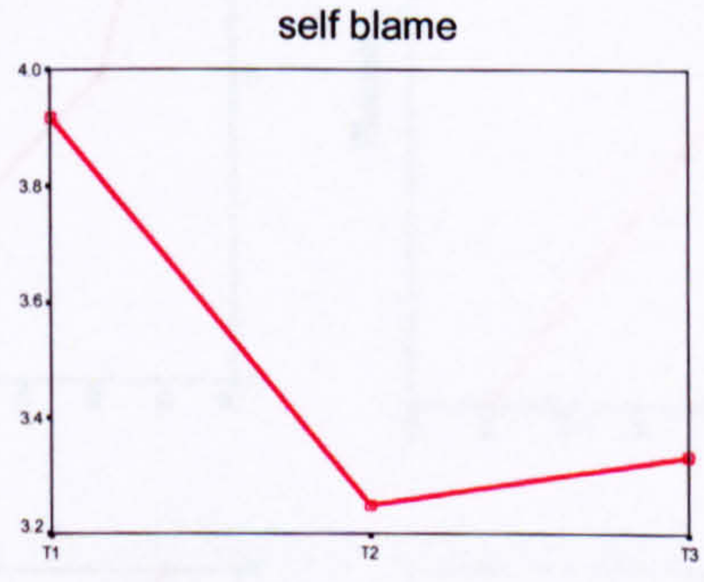
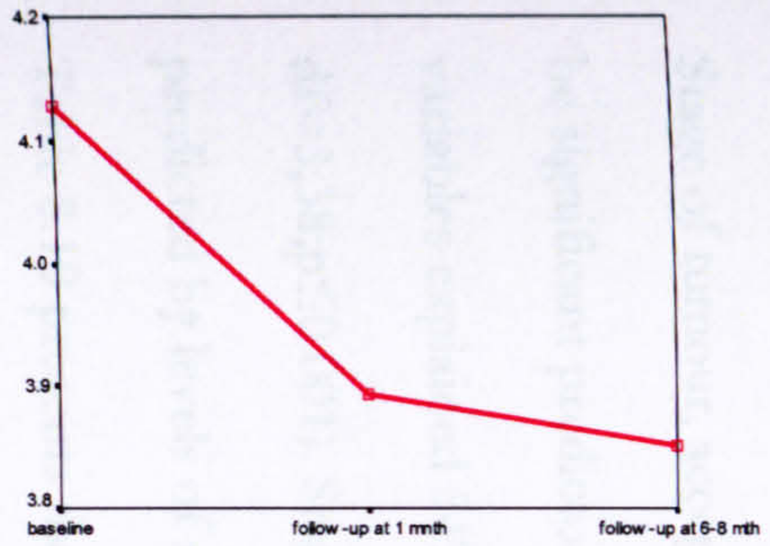
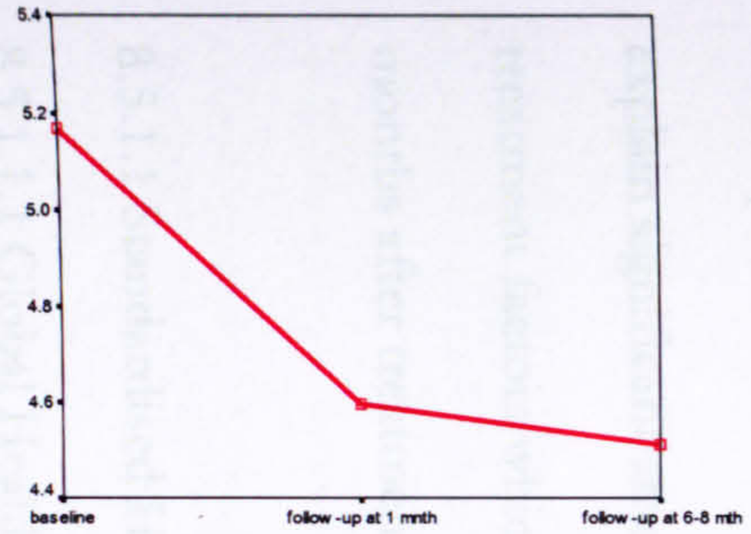


Figure 8.3: Plots of mean scores for coping strategies used over time (continued)

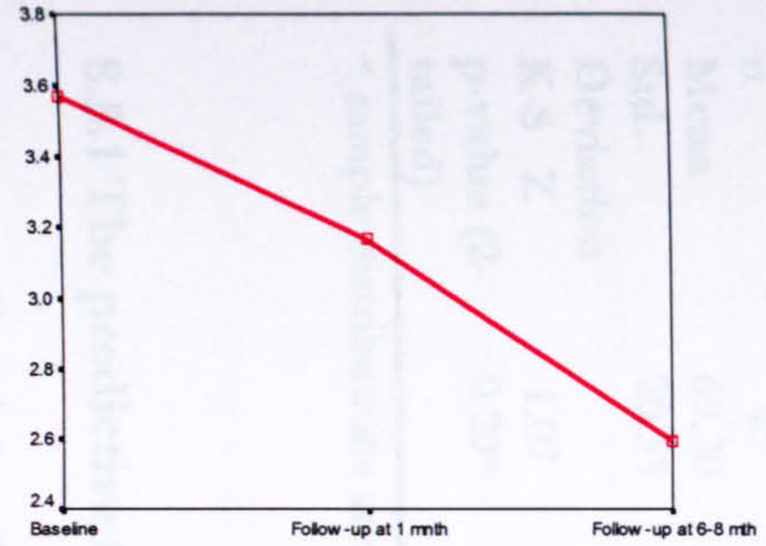
Self-Distraction



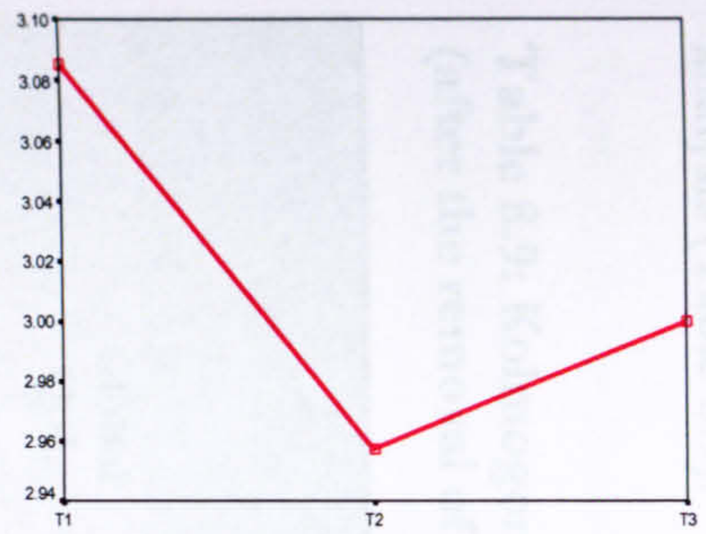
active coping



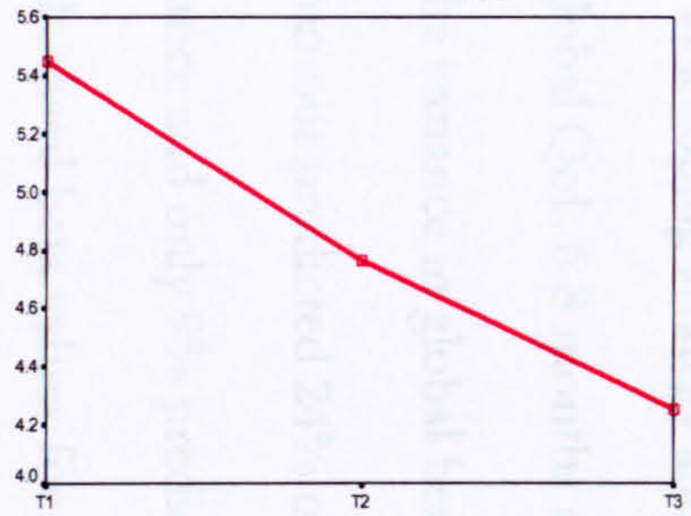
Denial



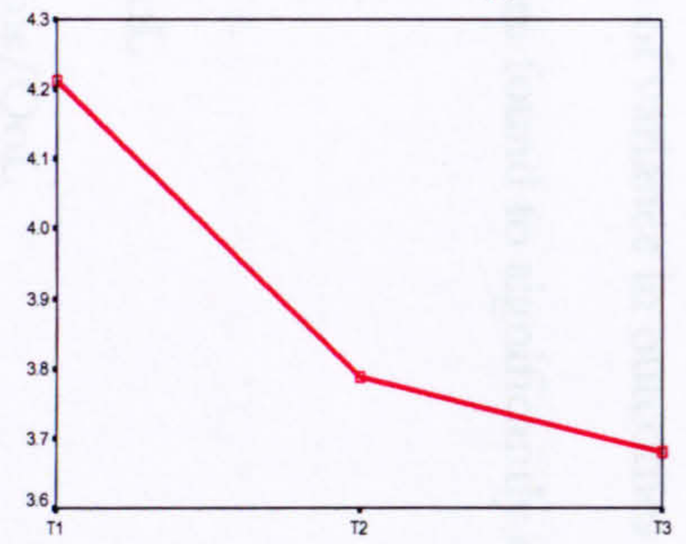
Substance use



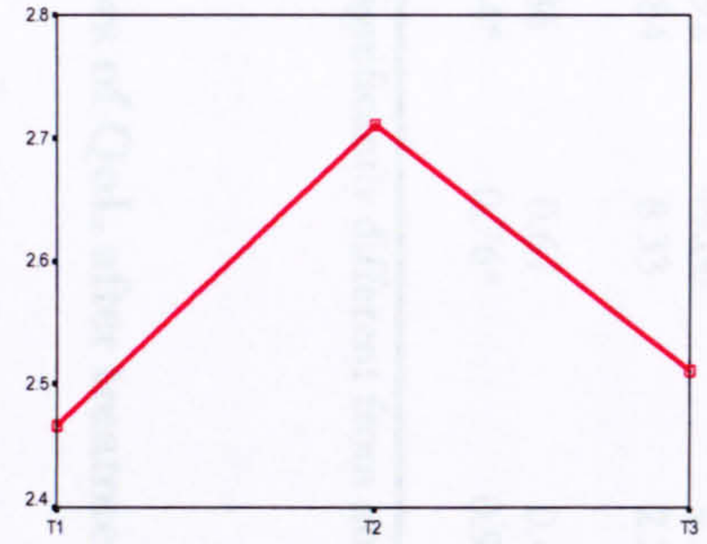
Use of Emotional Support



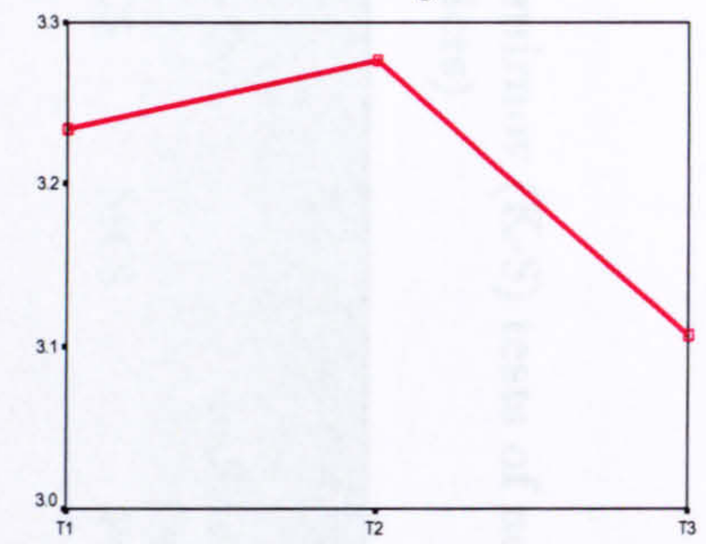
Use of Instrumental Support



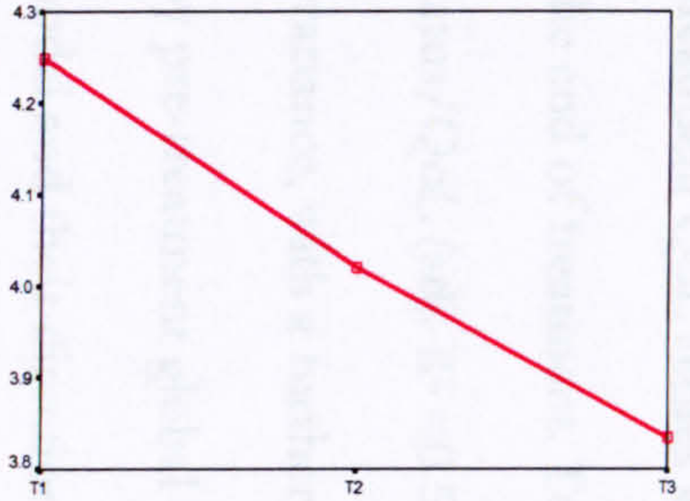
Behavioural disengagement



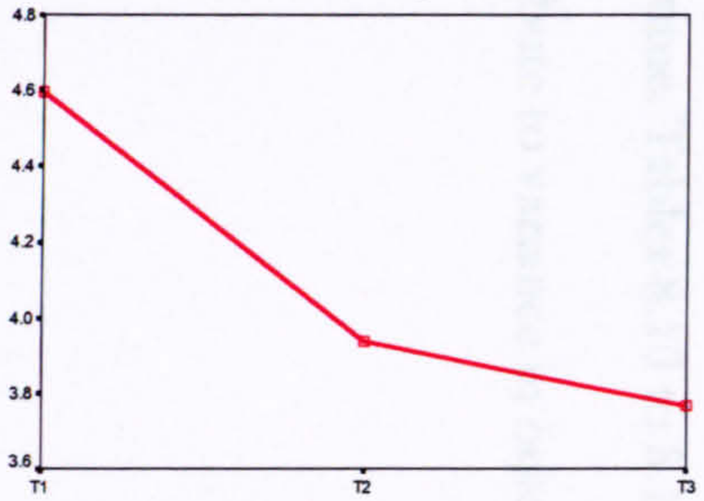
Venting



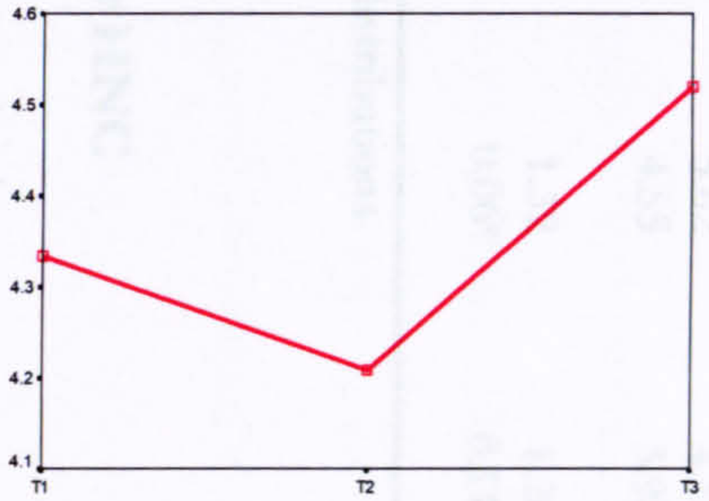
Positive reframing



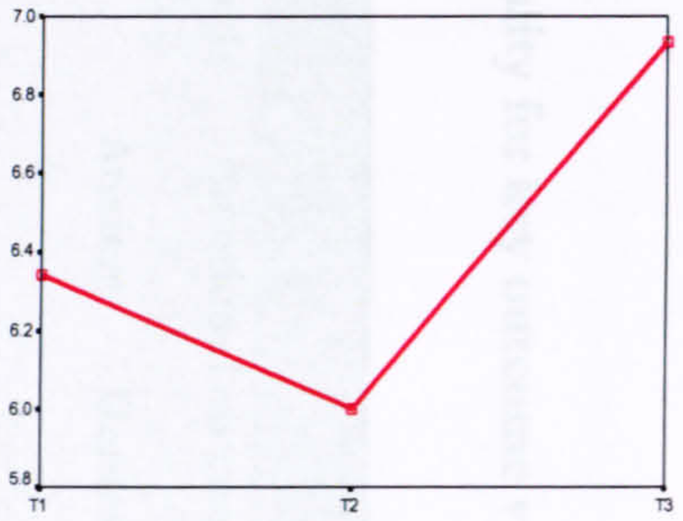
Planning



humour



Acceptance



Kolmorogov-Smirnov tests demonstrated that key outcome variables at T3 were not sufficiently different from a normal distribution to be problematic for entry into parametric analysis (Table 8.9).

Table 8.9: Kolmogorov-Smirnov (K-S) tests of normality for key outcome variables (after the removal of outliers)

	Outcome variable					
		HR-QoL		Individualised QoL	Emotional outcomes	
	Global QoL	PCS	MCS	PGI	Anxiety	Depression
n	46	49	49	40	50	49
Mean	69.20	42.92	49.00	4.34	5.62	4.39
Std. Deviation	20.33	11.84	8.33	2.22	4.55	3.98
K-S Z	1.07	0.86	0.67	0.45	1.32	1.20
p-value (2-tailed)	0.20*	0.44*	0.76*	0.99*	0.06*	0.11*

* sample distributions are not significantly different from normal distributions

8.5.1 The predictive factors of QoL after treatment for HNC

It was predicted that illness and treatment perceptions assessed prior to treatment would not explain significant amounts of variance in outcomes over time. Tables 8.10 to 8.15 show pre-treatment factors which were found to significantly contribute to variance in outcomes 6-8 months after treatment.

8.5.1.1 Standardised HR-QoL

8.5.1.1.1 Global Health status/QoL

Stage of tumour, acceptance as a coping strategy and pre-treatment QoL scores were found to be significant predictors of global QoL 6-8 months after the end of treatment. Together these variables explained 54% of the variance in global health status/QoL (adj. $R^2 = 0.54$; $F = 17.23$; $df = 3,38; p \leq 0.001$). Stage of tumour predicted 24% of the variance, with a further 21% predicted by levels of acceptance and only 9% predicted by pre-treatment global QoL scores. Table 8.10 presents the standardised beta values for the model and their direction of indicated

that lower levels of global QoL were associated with later stage tumours, high levels of acceptance coping, and as expected, lower levels of global QoL prior to treatment.

Table 8.10: Predictive factors of Global health status/ QoL after treatment (n=46)

Predictive factors assessed at baseline	Std β
Stage of tumour	-0.51**
Acceptance coping	-0.43**
Pre-treatment Global QoL scores	0.33*

Overall Model: R^2 *=0.58; adj.* R^2 *=0.54; F=17.23; df=3,38* **
*p<0.005, **p≤0.001

8.5.1.1.2 Physical Component Summary (PCS) Scores

Approximately two-thirds of physical component summary scores were predicted by two factors: pre-treatment PCS scores and gender (adj. R^2 =0.66; F=46.63; df=2,54;p≤0.001). In the regression, 58% of the variance in HR-QoL related to physical components was accounted for by PCS scores at baseline and an additional 8% was accounted for by gender. Being female was associated with worse PCS scores over time (Table 8.11).

Table 8.11: Predictive factors of PCS scores after treatment (n=49)

Predictive factors assessed at baseline	Std β
Pre-treatment PCS scores	0.75**
gender	-0.29**

Overall Model: R^2 *=0.68; adj.* R^2 *=0.66; F=46.63; df=2,45***
*p<0.005, **p≤0.001

8.5.1.1.3 Mental Component Summary (MCS) Scores

Only about a third of the variance in HR-QoL related to mental components was predicted by three variables of: anxiety, optimism and satisfaction with information (adj. R^2 =0.33; F=8.27; df=3,42; p<0.005). Levels of anxiety accounted for 19% of the variance, 8% was accounted for by levels of optimism, and a further 6% by satisfaction with information. The direction of

standardised beta values indicate that higher MCS scores were associated with lower levels of anxiety, higher levels of optimism and greater satisfaction with information.

Table 8.12: Predictive factors of MCS scores after treatment (n=49)

Predictive factors assessed at baseline	Std β
Anxiety	-0.41**
Optimism	0.28*
Satisfaction with information (amount & content)	0.27*

Overall Model: R^2 *=0.37; adj.* R^2 *=0.33; F=8.27; df=3,42* **
*p<0.05, **p<0.005

8.5.1.2 Individualised QoL

Fifty percent of the variance in individualised QoL scores was predicted by pre-treatment PGI scores and stage of tumour (adj. R^2 =0.48; F=16.31; df=2,3; p<0.001). The majority of this variance was accounted for by pre-treatment levels of QoL (40%) and a further 8% was accounted for by stage of tumour. Later stages of tumour were associated with lower levels of QoL (Table 8.13).

Table 8.13: Predictive factors of individualised QoL after treatment (n=40)

Predictive factors assessed at baseline	Std β
Pre-treatment PGI scores	0.58**
Stage of tumour	-0.32*

Overall Model: R^2 *=0.51; adj.* R^2 *=0.48; F=16.31; df=2,31* **
*p<0.05, **p<0.001

8.5.1.3 Emotional Outcomes

8.5.1.3.1 Depression

Levels of depression after treatment were predicted by illness beliefs, coping strategies and satisfaction with information (adj. R^2 =0.67; F=24.66; df=4,42; p<0.001). Stronger beliefs in the illness lasting a long time, high levels of self-blame for the illness, low levels of satisfaction

with information and high levels of acceptance at baseline, were related to high levels of depression over time. Timeline beliefs and self-blame accounted for the highest amounts of variance in depression (28% and 21% respectively).

Table 8.14: Predictive factors of depression scores after treatment (n=49)

Predictive factors assessed at baseline	Std β
Timeline	0.51*
Self-Blame	0.42*
Satisfaction with information (amount & content)	-0.34*
Acceptance	0.33*

Overall Model: $R^2 = 0.70$; *adj.* $R^2 = 0.67$; $F = 24.66$; $df = 4,42$*
*p<0.001

8.5.1.3.2 Anxiety

The only factor to prove predictive of levels of anxiety 6-8 months after treatment was anxiety at baseline (adj. $R^2 = 0.27$; $F = 19.37$; $df = 1,48$; $p < 0.001$).This factor accounted for 27% of the variance in anxiety (Table 8.15).

Table 8.15: Predictive factors of anxiety scores after treatment (n=50)

Predictive factors assessed at baseline	Std β
Pre-treatment anxiety scores	0.54*

Overall Model: $R^2 = 0.29$; *adj.* $R^2 = 0.27$; $F = 19.37$; $df = 1,48$ **
*p<0.001

In conclusion, hypotheses 1a, b and d were accepted, as illness and treatment beliefs were not significant predictors of standardised HR-QoL, individualised QoL or anxiety. However, hypotheses 1c was rejected as Timeline beliefs at baseline were significantly predictive of levels of depression 6-8 months after treatment.

8.5.1.4 Tests for normality, linearity, homoscedasticity, multicollinearity and independence of residuals

For each of the six models, plots of standardised residuals against standardised predicted values were fairly random and evenly dispersed, therefore, data were probably within the limits for meeting assumptions of homoscedasticity and linearity. Histograms of standardised residuals were normally distributed (excluding individualised QoL), indicating that assumptions had been met for normally distributed errors (individualised QoL displayed non-normally distributed errors). The P-P plots of normally distributed residuals represented normal distributions. The assumption of independent errors was met with Durbin-Watson statistics within the acceptable range. Collinearity statistics of tolerance and variance inflation factors (VIF) were well within acceptable ranges (>0.2 and <10 respectively) indicating that the assumptions of no multicollinearity were met for each model.

8.5.2 What factors predict whether expectations are fulfilled after treatment?

It was hypothesised that fulfilment of expectations after treatment would not be predicted by pre-treatment illness and treatment perceptions. This was rejected as two of the three fulfilled expectations assessed 6-8 months after treatment were predicted by particular pre-treatment illness and treatment beliefs. As mentioned previously, specific expectations regarding the outcome of treatment and the extent of recovery were dichotomised into actual experience being 'worse than expected' or 'better/the same as expected'. The third measure assessing the extent to which expectations regarding the whole treatment and recovery period overall had been fulfilled by actual experience was treated as a categorical variable.

The first logistic regression analysis (Table 8.16) demonstrated that 62% of the variance in outcome expectations (Nagelkerke R^2=0.62) was due to three factors of: undergoing chemotherapy; perceptions of the negative consequences of the disease; and substance use coping (χ^2=19.49;df=3;p<0.001). However, only perceptions of the negative consequences of

the illness were significant ($p<0.05$). Patients with strong perceptions of the negative consequences of the illness were 50% less likely to report that their expectations had been fulfilled post-treatment (OR=0.5;95% CI:0.2-0.9).

Table 8.16: Pre-treatment factors predicting fulfilment of expectations regarding the outcome of treatment

Pre-treatment factor	*B*	SE	Wald	Exp (B)	95% CI Lower Upper
Chemotherapy	-2.60	1.51	2.96	0.1	0.01-1.4
Consequences	-0.79	0.37	4.71	**0.5**	0.2-0.9*
Substance Use	-0.61	0.32	3.52	0.6	0.3-1.0

* $p<0.05$

Analysis examining predictors of the fulfilment of expectations regarding the extent of recovery demonstrated that four pre-treatment factors contributed to a significant model ($\chi^2=18.3;df=4;p\leq0.001$) explaining 56% of the variance (Nagelkerke $R^2=0.56$). Only gender and MCS QoL scores proved significant, indicating that females were 96% less likely than males to report having their expectations regarding the extent of recovery to date fulfilled, and patients with higher MCS scores before treatment were a fifth more likely to have their expectations met than those with lower MCS scores (Table 8.17).

Table 8.17: Pre-treatment factors predicting fulfilment of expectations regarding the extent of recovery 6-8 months after treatment

Pre-treatment factor	*B*	SE	Wald	Exp (B)	95% CI† Lower Upper
Gender	-3.34	1.57	4.54	**0.04**	0.002-0.8*
Stage	-1.84	1.15	2.54	0.16	0.02-1.5
Chemotherapy	-4.29	2.61	2.70	0.01	0.01-2.3
Mental Component Summary score	0.21	0.1	4.96	**1.2**	1.03-1.5*

* $p<0.05$

Analysis of predictive factors for the fulfilment of overall expectations demonstrated that a quarter of the variance in outcome could be explained by pre-treatment factors of: humour as a

coping strategy; emotional response to the illness and satisfaction with the form and timing of information received prior to treatment (adj. R^2 =0.25; F=7.94; df=3,60;p<0.001). Humour accounted for 12% of the variance, emotional response 11%, and satisfaction with information accounted for a further 5%. Higher ratings of expectations being fulfilled by experience were associated with a less marked emotional response to the illness, less use of humour as a coping strategy and higher levels of satisfaction with information prior to treatment (Table 8.18).

Table 8.18: Pre-treatment factors predicting fulfilment of overall expectations 6-8 months after treatment

Predictive factors assessed at baseline	**Std β**
Humour (coping strategy)	-0.36**
Emotional response	-0.36**
Satisfaction with information (form & timing)	0.23*

Overall Model: R^2 =0.28; adj. R^2 =0.25; F=7.94; df=3,60 **
*p<0.005, **p≤0.001

8.5.3 Is there any evidence for a 'response-shift' between baseline and post-treatment scores

Patients identified a variety of areas that were affected by their HNC both before and after treatment. Table 8.19 shows the areas listed by each patient as top priority before treatment and 6-8 months after. These included factors that were specific to HNC, for example, resulting problems with speech and communication, and also more general areas such as fear of recurrence and ability to work and maintain family life. Many of these areas were included in the domains of the generic and disease specific QoL questionnaires, although many of the areas mentioned by patients were more specific, for example, letting people down, and not being able to sing anymore.

After 6-8 months, eleven patients reported the same domain as being affected by their HNC and being their top priority, whereas 34 patients reported a different area affected. This was

interpreted as undergoing a reprioritisation in the areas of QoL that were currently most important to the patient. However, as illustrated by the areas of QoL reported in Table 8.19, reprioritisation could not necessarily be considered as adaptive, but reflective of changing functional problems as a result of treatment. Despite this, the null hypothesis that there would be no evidence of reprioritisation in QoL domains between baseline and post treatment assessment was rejected.

There was no evidence for any association between the occurrence of reprioritisation and either a negative or positive change in overall PGI score over time ($r=-0.04;n=32;p>0.05$). However, exploratory analysis of clinical, treatment and psychological factors found a significant positive association between a change in priority over time and depression at 6-8 months ($r=0.48;n=44;p\leq0.001$), indicating that the occurrence of reprioritisation was associated with higher levels of depression at the same time point. There was no correlation between level of optimism and reprioritisation.

Table 8.19: Areas of top priority reported by patients in the PGI, pre-treatment and post treatment

Patient	Area of top priority before treatment	Area of top priority 6-8 months after treatment	Evidence of reprioritisation
1	Problems with speech	Speech	-
2	Social life	Pain	+
3	Uncertainty	Social life	+
4	Eating	Loss of pre-treatment levels of energy	+
5	Unable to go to work	Loss of earnings	-
6	Communication	Communication	-
7	No areas affected	Fear of recurrence	+
8	Fear of recurrence	Concern over recurrence	-
9	Ability to look after grandchildren	Climbing stairs	+
10	Concern for family	Tiredness	+
11	Family life	Not able to work	+
12	Difficulty eating	Fear of recurrence	+
13	Difficulty eating	Not eating	-
14	Difficulty eating	Can't be bothered with anything	+
15	Leaving my husband alone to cope	Difficulty eating some meats	+
16*	Fear of recurrence	Concern over future	+
17	Eating some foods	People looking at me	+
18	People staring	Eating more quickly	+
19	Cannot get support to move home	Depression	+
20	Family life	Family life	-
21	Concern for my two dogs	Hearing – deafness on one side	+
22	Do not feel like sex	Difficulty eating	+
23	Ability to work	Interests	+
24	Nothing affected	Nothing affected	-
25	Difficulty eating	Difficulty eating	-
26	Talking	Feeling uncertain	+
27	Being depressed	Social life	+
28	Feeling uncertain	Difficulty eating	+
29	Nothing affected	Can not eat at all now	+
30	Nothing affected	Not able to work	+
31	Speech	Speech	-
32	Difficulty eating	Difficulty eating	-
33	Letting people down	Financial problems	+
34	Poor energy	Singing –husky voice now	+
35	General day to day family life	No areas affected – life is great!	+
36	Not able to do job	Much less energy	+
37	Fear for family/children	Social life	+
38	Feeling uncertain	Social life	+
39	Concern about operation	Fear of recurrence	+
40	Concern over future	Family life	+
41	I get on with life but feel depressed at times	Fear of recurrence	+
42	Concern over recovery in hospital	Concerns over time taken for neck scars to fade	-
43	Difficulty working	Surprise at collarbone looking prominent and ugly	+
44	Tiredness	Eating	+
45	Being dependent on others	Difficulty with swallowing food	+

* Alternatively, this could be interpreted as being the same construct.

8.5.4 Predictors of study drop-out

It was hypothesised that there would be no differences in baseline characteristics between patients who dropped out of the study by the last follow-up assessment and those that did not. This hypothesis was rejected. The only baseline psychological factors found to be significantly associated with study completion were illness and treatment beliefs. In particular, illness identity ($z=-1.97$; $p=0.05$), beliefs about the consequences of the illness ($z=-2.40$; $p=0.02$), emotional representations ($z=-2.22$; $p=0.03$) and beliefs about the necessity of treatment ($z=-2.35$, $p=0.02$) were associated with completion of measures at 8 month follow-up. Examination of the mean values indicated that patients reporting more symptoms related to HNC, strong beliefs about the negative consequences, strong emotional representations, and strong beliefs in the necessity for treatment to their health, were more likely to drop-out of the study. There were no differences evidenced for coping strategies used, levels of optimism, anxiety or depression, satisfaction with information or any differences in QoL or pain before treatment ($p>0.05$).

Of the variables: stage of cancer, type of treatment, illness identity, consequences, emotional representations and necessity entered into the regression model, 49% of the variance in drop-out was predicted by factors of, emotional representation, perceptions of the necessity of treatment and tumour stage ($\chi^2=32.97$;$df=5$;$p<0.001$). However, only perceptions of the necessity of treatment and stage of cancer were significant (Table 8.20), indicating that patients with strong beliefs about the necessity for treatment were 30% more likely to drop out of the study than those with weaker beliefs. Patients with stage 4 tumours were 43 times more likely to drop out of the study compared to those with stage 1 tumours.

Table 8.20: Baseline factors predicting dropout of study 8 months after treatment

	B	SE	Wald	Exp (B)	95% CI† Lower Upper
Emotional representations	0.20	0.12	2.70	1.2	1.0-1.5
Necessity of treatment	0.27	0.14	3.97	**1.3**	1.0-1.7*
Stage 1†	-	-	-	-	-
Stage 2	2.24	0.99	5.09	**9.4**	1.3-65.9*
Stage 3	0.65	1.16	0.31	1.9	0.2-18.4
Stage 4	3.77	1.02	13.72	**43.3**	5.9-317.6**

† reference group
* $p<0.05$; **$p<0.001$
(Hosmer & Lemeshow Test: $\chi^2 = 5.75$;df=8;$p>0.05$)

8.6 DISCUSSION

The main aims of this repeat measures design study were to establish key changes in variables over time and to investigate whether components of the SRM were predictive of long-term outcomes.

8.6.1 Changes over time in key factors

Generally, QoL worsened one month post-treatment as compared to baseline levels. However, 6-8 months after the end of treatment, levels of global QoL, were better than baseline levels. Although levels of anxiety remained higher than levels of depression at all assessments, levels quickly diminished and plateaued after treatment. Conversely, levels of depression increased as physical functioning worsened but showed signs of gradually decreasing 6-8 months after treatment. These results are consistent with previous findings (Chawla et al., 1999; de Graeff et al., 1999b; Hammerlid et al., 2001b; Kohda et al., 2005), whereby most treatment associated symptoms increase and are most likely to be responsible for the temporary deterioration of QoL and increase in depressive symptoms.

Although patients reported a better overall QoL longer term than at baseline, when they may have been experiencing symptoms of their disease, general HR-QoL scores as assessed by the SF-12 (in particular physical functioning) were still shown to be poorer at 6-8 months than general (US) population levels (not age or gender adjusted). The last measurement was taken

relatively soon after the end of treatment (6-8 months) and it is not known whether QoL continues to increase until it reaches levels shown by the general population and, if so, how long this takes to occur. It has previously been suggested that any improvements to HR-QoL occur in the first 12 months after treatment with very little change afterwards (de Graeff et al., 2000b; Morton, 2003; Rogers et al., 1999). It is of interest to note that despite similar baseline levels between the two SF-12 component summary scores, and a worsening of physical functioning in particular, HR-QoL related to mental functioning increased significantly between one month and 6-8 months after treatment. This demonstrates that patients' QoL does not necessarily worsen in line with physical difficulties, depending on what aspects of QoL are being assessed. Patients demonstrated longer-term problems with specific symptoms related to their treatment, such as; trouble with eating due to sticky saliva and having a dry mouth, and loss of functioning of the shoulder and arm. However, the use of painkillers decreased and as mentioned previously, emotional /mental functioning improved.

This study also highlighted the dynamic nature of illness and treatment representations, with significant changes over time shown in key patient beliefs. Perceptions of the necessity of treatment significantly increased over time and correspondingly, patients understanding of their illness significantly increased too. Interestingly, patients' beliefs about the personal controllability of their illness significantly decreased from baseline perceptions. In addition to these changes, patients' perceptions of the consequences of their illness were also less negative. These changes indicate that patient's beliefs may be modifiable and independent to illness identity (and levels of symptoms they are currently experiencing). Not much is known about how beliefs change over time and what motivates change. However, the significant changes highlighted in this study suggest that beliefs may be associated with positive adaptive processes.

8.6.2 Predictive factors of long-term QoL (6-8 months after the end of treatment)

It was hypothesised that illness and treatment perceptions assessed at baseline would not explain a significant amount of variance in longitudinal outcomes. Illness and treatment perceptions were not found to be significant predictors of either: standardised HR-QoL (as assessed by SF-12 PCS and MCS scores and EORTC QLQ-C30 Global QoL/health status scores), individualised QoL, or levels of anxiety, and therefore null hypotheses relating to these outcomes were accepted. However, levels of depression 6-8 months after the end of treatment, were predicted by beliefs regarding the expected duration of the illness (Timeline beliefs) and therefore, hypothesis 1c was rejected.

Coping strategy was found to be significantly associated with only two outcome measures; Global health status/QoL and depression. Levels of acceptance coping were negatively related to Global health status/QoL and positively related to depression indicating that lower levels of acceptance were reported by individuals experiencing high levels of QoL and low levels of depression. This may appear to be contrary to expectations but, it may be that acceptance is related to severity of symptoms and impairment resulting from the cancer, or indeed states of denial. Patients reporting low levels of depression and high QoL may be un-accepting of their cancer due to denial or because they have very little by way of signs and symptoms to remind them of their cancer diagnosis. The literature also demonstrates that patient beliefs may be more predictive of outcomes than coping mechanisms (Heijmans, 1998; Moss-Morris et al., 1996; Orbell et al., 1998; Scharloo et al., 1998). However, previous studies have shown that coping is related to HR-QoL (when beliefs are not assessed) (Hassanein et al., 2001) and have suggested that pre-treatment coping strategies may be an important focus for intervention (Allison et al., 2004; Chaturvedi, Shenoy, Prasad, Senthilnathan, & Premlatha, 1996; List et al., 2002).

Depression and outcome were not found to be related as other prospective studies assessing these relationships within 12 months of treatment have suggested (D'Antonio et al., 1998; de Graeff et al., 2000b). This indicates that when other psychological variables are taken into account, the relationship between depressive symptoms and QoL diminishes, and that QoL is not just a proxy indicator of depression.

In a longitudinal study of fifty males undergoing surgery for HNC, the objective level of the threat (i.e. the extent of impairment resulting from surgery or the prognosis), was not correlated with subjective levels of anxiety. This indicated that it is the way individuals interpret the health threat that is influential to emotional outcomes such as anxiety or depression (Demaddalena & Zenner, 1991). It was also found that information about the outcome of treatment was not enough to reduce anxiety. It was suggested that it is also necessary to enhance a patient's feeling of personal control and this could be achieved through continual contact with the doctor. The idea that patient control is a precursor to reducing anxiety among HNC patients is also reinforced by work by Dropkin (2001), whose study of 75 HNC patients demonstrated that as patient's perception of control increases, dependence decreases (as shown by levels of self-care) and anxiety reduces (Dropkin, 2001). However, this was not supported by the present research whereby only pre-treatment levels of anxiety were predictive of longitudinal anxiety. However, the analysis demonstrated that only 27% of the variance in post-treatment anxiety was explained by pre-treatment levels and therefore, other unknown factors may have more of an influence.

Gender and stage of cancer were found to be predictors of outcomes such as Global QoL, PCS scores, and individualised QoL. However, no other socio-demographic or clinical factors were found to be significant predictors. Other authors have reported the significance of alcohol abuse as predictive of QoL (Sehlen et al., 2002), and although we did not explicitly collect this

data and use it for analysis, the coping strategy of 'using substances to cope' did not prove to be significantly associated.

8.6.3 Factors predictive of the fulfilment of expectations after treatment

Little has been published on expectations in HNC patients and as such the measures that were used in this study were novel. The results of this study demonstrated that the only pre-treatment factors associated with the fulfilment of expectations regarding the outcome of treatment (cosmetic and/or physical effects of treatment, not prognosis related) were perceptions about the negative consequences of the illness. Patients who believed, prior to treatment, that their illness would have strong negative consequences were 50% less likely to report that their expectations had been fulfilled 6-8 months after the end of treatment. Therefore, hypothesis 2 was rejected. Optimism or severity of cancer, were not significant factors. A gender difference was observed when examining the factors associated with expectations regarding the extent of recovery 6-8 months since treatment. Females and those with low mental component summary scores (MCS) at baseline were less likely to report having their expectations about recovery fulfilled. Most interestingly, a relationship between satisfaction with information at baseline and the fulfilment of expectations overall was demonstrated.

8.6.4 Implications for intervention

Patients' beliefs and perceptions about their illness have successfully been the focus for interventions in a variety of illnesses (Candy, Chalder, Cleare, Wessely, & Hotopf, 2004; Petrie et al., 2002). This chapter has demonstrated that illness perceptions prior to treatment, in particular, beliefs about how long the illness will last, the perceived negative consequences of the illness, and the emotional response, are related to outcomes after treatment. It is these beliefs that could be used as a basis for intervention in the time period between diagnosis and shortly after treatment in order to maximise longitudinal outcomes.

In addition, satisfaction with information was found to be associated with outcomes of depression, Mental Component Summary scores, and fulfilment of expectations overall. The information giving process could be developed to encourage more realistic (but positive) expectations through more contact with specialist nurses and 'expert' patients. However, research has suggested that it is the inferences individuals make about the information that determines levels of distress rather than the meanings the information giver intends to convey. It has been documented that people are more likely to experience anxiety if the information is interpreted as threatening (Teasdale, 1993). This indicates that people interpret the information they have been given within their own framework of ideas and theories of their illness, which is why it is of importance to access patients' views about their illness and treatments in relation to their satisfaction with information prior to and during treatment.

8.6.5 The usefulness of the PGI as a tool for eliciting 'response-shift'

The concept of response shift has been found to be of potential importance when measuring changes in health state over time. It has previously been suggested that attitudes towards a particular construct such as QoL do not remain constant over time and individuals have been found to place differing emphasis on the importance of domains and this may change over time (McGee, O'Boyle, Hickey, O'Malley, & Joyce, 1991; O'Boyle, McGee, Hickey, O'Malley, & Joyce, 1992). One of the major difficulties with attempting to assess response shift is that it is essentially an abstract concept that is difficult to measure directly (see Chapter 3, part 3.4.2). The process of response shift in the current research was operationalised as a change in an individual's priorities over time, and the PGI was used to attempt to assess changes in values and priorities between diagnosis and 6-8 months after treatment.

Previous research using the PGI has yielded mixed opinions as to its potential usefulness in clinical practice. Many studies, including the original developmental study, have reported that

not all respondents are able to complete the PGI correctly (Ruta, Garratt, & Russell, 1999; Ruta et al., 1994) and this was found to be associated with lower levels of education and lower levels of physical functioning (Ruta et al., 1999). Since the original version (Ruta et al., 1994), a simpler version incorporating a prompt list has been developed (used in the current study) in order to maximise response rates. However, in concordance with the current study, research using the revised version has shown no improvement in response rates (MacDuff et al., 1998) and thus the representativeness and reliability of the PGI is still under question.

The current results from the PGI suggest that individuals list the areas of their lives that are most affected by their condition and not necessarily areas that are most important to them. This may be because respondents have difficulty understanding the instructions, or separating health related quality of life from other factors which compromise their overall life quality. In addition, it has been argued that patients may not realistically be able to isolate the effect of one medical condition on their lives, over and above other unrelated conditions they may have (MacDuff, 2000). Based on the present results, hypothesis 3 was rejected, however, the finding of a positive relationship between reprioritisation and depression in the current chapter suggests that 'changes in priority' are more likely to be indicative of an increase in negative cognitions due to problems developing in different areas, rather than as a positive process of life reprioritisation.

A more useful method for assessing response shift, in terms of reprioritisation, may be to examine changes in key illness perceptions over time. For example, perceptions of the negative consequences of the illness were found to significantly decrease after treatment. This may be indicative of individuals undergoing a period of self-actualisation and positive growth and may be more representative of the concept of reprioritisation than the PGI is able to achieve. Further research is needed to test whether changes in perceptions of consequences are related

to processes of reprioritisation and other related constructs such as 'benefit finding' (see Chapter 3).

8.6.6 Factors predictive of individuals dropping out of study

It was hypothesised that there would be no differences in baseline characteristics between patients who completed measures 6-8 months after the end of treatment and those that did not. This was rejected as baseline illness and treatment beliefs and stage of cancer were found to significantly predict full study concordance amongst those recruited at baseline. Tumour stage, emotional representations and beliefs about the necessity of treatment predicted 49% of the variance in drop-out, although only factors of tumour size and necessity of treatment were found to be significant. It is intuitive that individuals with larger tumour stages are more likely to drop out for reasons such as entering a palliative phase or tumour recurrence, however, it is less easy to explain the reasons why people with stronger beliefs in the necessity of treatment should be more likely to drop-out. It may be that there is a strong but partially independent relationship between cancer severity (tumour stage) and need for treatment, thus those with larger tumours perceive more necessity for treatment.

8.6.7 Limitations

This study had a number of limitations, generic to QoL research and more specific to this study in particular.

A problem with QoL data in general, is that there is an inherent bias towards those that are better off and indeed those that have survived. Follow-up data tends to be skewed towards those with earlier stage tumours and therefore less physical consequences of treatment. A comparison of those that were originally recruited into the study and those that remained at follow-up, demonstrated a significant difference in tumour stage, with those remaining in the

study being diagnosed with earlier stage tumours at the outset. Relatively large attrition rates for a number of reasons, limits the generalisability of the results.

The removal of outliers as a process prior to analysis may have meant that data were more generalisable, however, outliers tended to be patients who were significantly worse off. It could be argued that these are perfectly valid scores, however their non-removal would mean that any subsequent models would not provide a good fit for the remaining data.

A weakness of the study was that the follow-up period was relatively short (6-8 months after the end of treatment). This was due to time constraints and due to the varying and sometimes lengthy duration of the treatment. It would have been interesting to see whether relationships between psychological factors and outcomes remained stable over a longer time period.

A limitation of the current operationalisation of the SRM, measured at specific time points is that people's models of their illness and their response to illness and treatment are probably dynamic. The complexities of how these beliefs interact with outcomes are lost with the type of study employed. The feedback system of the SRM may be better captured using interview methodology in order to examine the nature and effects of appraisal processes. The same applies to the assessment of the response shift phenomenon.

A number of measures used in this study were unvalidated, such as the items assessing expectations, or preliminary validated, such as the satisfaction with information scales. As a result, analyses using these measures should be interpreted with caution.

8.6.8 Conclusions

The results from this chapter highlight the utility and limitations of the illness perceptions framework and the SRM as investigative tools to examine the potential relationships between

key psychological factors and outcomes. Although much of the variance in outcomes such as; individualised QoL, Physical Component Summary scores, and anxiety was explained by their respective baseline levels, Mental Component Summary scores, Global health status/QoL, depression and the fulfilment of expectations, were explained by the types of beliefs patients had and the method of coping employed. This is of potential importance in the planning stages of interventions based on factors other than un-modifiable clinical, treatment related, or socio-demographic factors.

It would be of further interest to investigate whether baseline factors found to be predictive of outcomes at six to eight months after treatment, were predictive of longer-term outcomes or whether the relationships between beliefs and outcomes change over time as suggested by the results of chapters 7 and 8. Further research could extend the study for longer than was feasible in the present study. This would have further implications for the utility of intervention at different time-points.

CHAPTER 9

STUDY OF POST-TREATMENT ADAPTATION AND SATISFACTION WITH LIFE AFTER CANCER: A CROSS-SECTIONAL COMPARISON STUDY USING THREE PATIENT SAMPLES AND A MATCHED NON-CLINICAL SAMPLE

9.1 INTRODUCTION

Despite the possibility of long-term functional consequences related to treatment of cancer of the head and neck, many studies have determined that cancer in general does not inevitably lead to long-term problems with psychological well-being and overall quality of life (Andrykowski *et al.*, 1996; De Haes & Knippenberg, 1985; Stiegelis *et al.*, 2003). The previous chapters have highlighted how size of tumour and physical functioning are not wholly responsible for patient's perceptions of their QoL pre- and post treatment, and in particular are not explanatory of ratings of depression and anxiety.

Despite the longitudinal study design used in the previous study, little is known about the cognitive and emotional adaptive processes that occur over a longer time period, and whether any changes in physical, social, cognitive, or emotional functioning significantly impact on an individual's self-perception or subjective well-being (SWB).

SWB is receiving increased attention as an important long-term outcome following illness or injury. SWB as a construct is thought to contain both an emotional component (which can be further divided into pleasant and unpleasant affect (Diener & Emmons, 1984)), and a cognitive-judgmental component, which is often referred to as life satisfaction (Andrews & Withey, 1976). The majority of research has focused on the assessment of affective well-being, with a plethora of measurement instruments that have been developed. For example, the Positive and Negative Affect Scale (PANAS) (Watson, Clark, & Tellegan, 1988) was developed to measure mood and affective well-being and there are many scales to measure unpleasant affect (e.g. depression).

9.1.1 The cognitive component of SWB: Life satisfaction

Less researched, however, is the wider issue of how life satisfaction is affected by illness. Shin and Johnson (1978) defined life satisfaction as a judgemental process, in which individuals assess the quality of their lives on the basis of their own unique set of criteria (Shin & Johnson, 1978). Based on this definition, life satisfaction can be considered a conscious cognitive judgement of one's life based on how well it matches up to their self-imposed standards.

Life satisfaction can be assessed on a global level or can focus more narrowly on aspects of life such as work, recreation or relationships. The justification for studying it at a more global level is that the narrower aspects tend to co-occur and it is not likely that people will have the same criteria for a 'good life'. The Satisfaction With Life Scale (Diener et al., 1985), used in this chapter, aims to measure global judgements of life satisfaction. The primary advantage of measuring life satisfaction with this approach is that the individual, rather than outside agencies, uniquely determines the comparative standard upon which the judgment of life satisfaction is based. While this flexibility may limit a clear understanding of the relative importance of specific life domains across populations, life satisfaction scores allow for comparisons in overall life satisfaction across different populations.

Due to time constraints with following-up a cohort of patients for longer in the main study, and the fact that no comparisons groups were used throughout the research, a cross-sectional comparison study involving longer term survivors was conducted. Comparisons between clinical and non-clinical samples can be problematic because of the use of specific quality of life measures, therefore, questions of a more general nature i.e. life satisfaction, were used to compare cancer survivors long-term satisfaction with life with other populations.

9.2 AIMS

There have been few studies examining cognitive and emotional adaptation over time, specifically in head and neck cancer patients. This chapter focuses on the longitudinal positive outcome of HNC, i.e. subjective well-being, as opposed to the assessment of HR-QoL, which primarily focuses on deviation away from health and functioning. This study intends to give some insight into whether over time, patients who survive HNC are satisfied with their lives in a wider context, not just from the perspective of functional status.

Therefore, the main aim of this chapter was to establish whether HNC patients in remission were at risk of long-term problems with adaptation, whilst establishing the factors that contribute to overall cognitive and emotional adaptation[11].

9.3 HYPOTHESES

More specifically, this study will test the following null hypotheses regarding the long-term impact of HNC on patients' perceptions of overall life satisfaction and whether clinical, physical or psychological factors are associated with cognitive and emotional adaptation.

1: Controlling for time since treatment, where appropriate, patients treated for cancer of the head region (excluding neck and throat cancer) will show cognitive adaptation by demonstrating similar levels of life satisfaction as:

a) Patients treated with surgery for a benign condition of the head;

b) Patients treated for early stage laryngeal cancer;

c) An age and gender matched non-clinical sample.

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[11] For the purposes of this study, cognitive adaptation was assessed by measuring levels of life satisfaction, and emotional adaptation was assessed using levels of anxiety and depression.

2. There will be no significant differences in levels of HR-QoL between patients treated for cancer of the head region and:

a) Patients treated with surgery for a benign condition of the head;

b) Patients treated for early stage laryngeal cancer;

c) An age and gender matched non-clinical sample.

This study will also test emotional adaptation issues in patients by assessing whether levels of psychiatric morbidity differed from the normal population. Depression and anxiety were assessed as markers of emotional adaptation.

3. Patients treated for cancer of the head region will show emotional adaptation by demonstrating similar levels of depression and anxiety to that of a normal population.

9.4 METHOD

9.4.1 Design

The study was a cross-sectional, postal questionnaire survey using three groups of patients and an age and gender matched non-clinical sample to represent a normative sample.

9.4.2 Procedure

All participants (excluding the age and gender matched non-clinical sample) were posted a patient information sheet (Appendix VIII), two consent forms, a reply paid envelope and the questionnaire consisting of the four measures detailed in section 9.3.4. Ten additional questions asked about socio-demographic factors, type of treatment (choice of four categories: surgery, radiotherapy, chemotherapy and other), time since last being treated, whether patients were still undergoing treatment, and whether any further illnesses or diseases had been diagnosed since being treated for the particular condition of interest. Participants recruited into the normative sample were asked whether they had suffered from any major illnesses / diseases in the last ten

years. Patients found to be still undergoing treatment for their condition were excluded from analysis.

9.4.3 Measures

The following measures were chosen to maintain continuity throughout the thesis. All the measures used were short in order to reduce responder burden and maximise response rates.

- **SWLS** (Diener *et al.*, 1985) to measure satisfaction with life.
- **SF-12v2** (Ware et al., 2002) to measure HR-QoL.
- **LOT-R** (Scheier et al., 1994) to measure personality in the form of life orientation/ optimism.
- **HADS** (Zigmond et al., 1983) to measure state depression and anxiety.

Full descriptions of the content and scoring of these measures can be found in the methods section in chapter 5.

9.4.4 Socio-demographic and clinical information

Socio-demographic variables of: age, gender, socio-economic status, marital status and ethnicity were assessed as described in the methods section. Clinical factors such as site and stage of cancer were assessed from patient notes or databases.

9.4.5 Participants

Four distinct samples were collected in order to test the main hypotheses relating to the impact of cancer diagnosis, type of treatment and time since treatment on life satisfaction. So that the influence of time since treatment could be minimized, all patient samples were at least 6 months post-treatment to allow for physical healing. The exact procedures for the identification and recruitment of each of the samples can be found in Chapter 5 part 5.1.2.2. A summary of each of these samples can be found in the following section.

9.4.5.1 Sample of patients treated for malignant tumours of the head

Patients were eligible if they were at least 6 months post treatment and had been diagnosed and treated for carcinoma of the head region, with no active recurrences or further treatment planned. Patients were recruited from Guy's Hospital.

9.4.5.2 Sample of patients treated for malignant tumours of the glottis/larynx (Throat cancer group)

The original aim of this comparison group was to recruit patients diagnosed with an early stage malignant tumour of the neck (larynx or glottis), who had been treated with radiotherapy only. This was to provide a cancer comparison group for the effects of surgery. In addition, these patients could also have provided a comparison for the effects of cancer stage on adaptation. However, due to problems with recruitment and the accuracy of hospital records, this sample was used as a comparison group for the effect of treatment for cancer with less severe aesthetic consequences to the facial region than a head cancer. Patients were recruited from Guy's Hospital and The Royal Marsden Hospital.

9.4.5.3 Sample of patients treated for benign salivary gland conditions

Participants within this sample consisted of patients treated by one oral surgeon (consistent with the head cancer patients) for a benign condition of the salivary glands requiring surgery. Inclusion criteria were that all patients should have been treated surgically and that the final histological diagnosis was benign.

9.4.5.4 Age and gender matched non-clinical sample

Participants were recruited from the community in the UK using a reputable market research agency (Research Initiatives Ltd) to provide a normative sample. This sample was purposefully matched with the sample of recruited head cancer patients on factors of age and gender.

9.4.6 Statistical analysis

The following clinical and socio-demographic variables were dichotomised: Stage of cancer (early (T1/T2) vs. advanced (T3/T4), marital status (living with partner vs. living alone), ethnicity (white vs. non-white) and highest qualification (none/ O' levels vs. further education and above). Type of treatment was also dichotomised (dummy coded) into 3 mutually exclusive groups: Surgery (S) only (Y/N); Radiotherapy (RT) +/- chemotherapy (CT) (Y/N); and S & RT/ CT (Y/N).

Sample group differences between measures were assessed with Kruskall Wallis tests with post-hoc comparisons for non-parametric data (see preliminary analysis section 9.5.4). As sample sizes were small, analyses between groups were conducted using non-parametric tests. Where regression models were constructed, correlational analyses were conducted first in order to reduce the number of factors entered into final models. Multiple linear regression analyses were conducted (using the stepwise method) to assess how much of the variance in satisfaction with life (or outcome variable of depression) was due to patient group or other explanatory factors. Method of entry and diagnostics were as described in previous chapters.

9.5 RESULTS

9.5.1 Response rates of the samples

The survival status of non-responder patients in the salivary gland sample and the HC sample was probed with a phone call to the GP listed in the notes. Many patients were not contactable and many had died since treatment. Two patients did not provide consent, one of which could not read and currently felt too ill to respond.

A more detailed breakdown regarding responders versus non-responders is presented in Table 9.1.

Table 9.1: Clinical and socio-demographic characteristics of responders versus non-responders

	Responders n (%)	Non-responders n (%)	Test statistic/ *p* value
Head cancer	115	47†	
Gender: male	73 (63)	26 (55)	χ^2=0.94; p>0.05
Mean age in years (sd; range)	64.2 (11.5;37-95)	68.3 (13.5;43-98)	t(160)=1.9; p>0.05
Cancer stage: Early T1/T2	69 (60)	20 (43)	V=0.12;
Advanced T3/T4	41 (36)	24 (51)	p=0.05
Benign salivary gland conditions	47	34‡	
Gender: male	25 (53)	17 (50)	χ^2=0.08; p>0.05
Mean age in years (sd; range)	52.5 (14.3; 17-82)	52.6 (20;23-94)	t(78)=-0.04; p>0.05
Early stage throat cancer	33	11	
Gender: male	32 (97)	11 (100)	χ^2=0.34; p>0.05
Mean age in years (sd; range)	67.3 (9.5; 53-86)	69.4 (14.8;39-100)	t(42)=0.55;p >0.05

† Includes non-responders/non-contactable and patients who refused to participate

‡Excluding those known to be deceased or not contactable.

There were no significant differences between responders and non-responders in gender (p>0.05) or age (p>0.05), however, non-responders tended to be older than responders in all samples (Table 9.1). A significant difference was found for stage of cancer at diagnosis in the main sample of patients with head cancer, whereby non-responders were more likely to have been diagnosed with more advanced stages of cancer (V=0.12; p=0.05).

9.5.2 Socio-demographic characteristics of study samples

Table 9.2 presents the socio-demographic characteristics of each group. Age of the whole sample ranged from 17 years to 95 years old. The majority (97%) of the throat cancer sample were male, approximately half of the benign salivary gland condition group and two thirds of the head cancer and normative sample were male. The throat cancer and the normative sample reported similar levels of educational attainment, with only 24% and 29% respectively, reporting having qualifications at GCE/A'level or above. In contrast, 53% of the participants in the benign salivary gland sample reported an educational level of GCE/A' level or above. Of the salivary gland patients, 70% were married or cohabiting and only 6% were widowed, in contrast to the other samples, which may have been due to the younger age of the salivary gland patients in comparison to the other groups. The majority of participants from all of the groups were of white UK ethnic origin.

9.5.3 Clinical characteristics of study samples

The sample of patients treated for cancer of the head was fairly heterogeneous, with mixed sites and stages of cancer, and treatment schedules (Table 9.3). The majority were tongue cancers (41%) and 60% were early stage (T1/T2). Time since last treated ranged from 1 to 12 years (mean=4.6 years). The majority of the sample (86%) had been treated with surgery (40% of these had been treated with surgery only). The throat cancer sample was more homogenous since all had been treated for early stage cancer of the glottis or larynx. Time since last treatment was similar to that of the other groups (mean=4.1 years, range from 1 to 10 years). The majority of the sample (97%) had been treated with radiotherapy (52% of these with radiotherapy alone). The sample treated for benign salivary gland conditions, was comprised of patients diagnosed with neoplasms of the parotid gland (83%) and other major salivary glands (17%). All had been treated with surgery and time since treatment ranged from 1 to 10 years (mean=4.2 years).

9.5.4 Preliminary analyses

Transforming variables improved kurtosis and skewness, however the majority of these were still not within an acceptable range and in addition Kolmorogov-Smirnov (K-S) tests proved significant ($p<0.05$). The main outcome variable of satisfaction with life (SWL) and explanatory variables of optimism, anxiety and depression still proved non-normally distributed after transformation, however, values of skewness were within an acceptable range and K-S statistics, although significant, were low. Therefore, it was decided to proceed with subsequent multivariate analyses using SWL as the outcome variable. Indeed neither the dependent variable or the independent variables have to conform to the assumptions of normality if the number of cases included is large (i.e. over 40 cases per IV) (Tabachnik et al., 1996).

The impact of negative kurtosis on estimates of the distribution is considered to be minor with samples of greater than 100, moreover, the impact of positive kurtosis is insignificant in sample sizes greater than 200 (Tabachnik et al., 1996). Therefore, the kurtosis of the variable distributions in this sample was not of importance given the main sample sizes used for regression purposes were of between n=195 to approximately n=300. Age was found to be normally distributed without the need for transformation.

Table 9.2: Socio-demographic characteristics of study samples

	Head cancer (n=115)	Throat cancer (n=33)	Benign salivary gland conditions (n=47)	Non-clinical sample (n=115)
Mean age (SD: range)	64.2 (11.5:37-95)	67.3 (9.5; 53-86)	52.5 (14.3; 17-82)	61.0 (11.5:37-85)
	n (%)	**n (%)**	**n (%)**	**n (%)**
Gender				
Male	73 (63)	32 (97)	25 (53)	74 (64)
Female	42 (37)	1 (3)	22 (47)	41 (36)
Highest educational qualification				
None	50 (44) *	21 (64)*	11 (23)	59 (51) *
GCSE/ O levels	21 (18)	2 (6)	11 (23)	21 (18)
GCE/ A levels/ similar	11 (10)	1 (3)	10 (21)	10 (9)
Higher Education/ similar	13 (11)	3 (9)	1 (2)	8 (7)
Degree/ similar	14 (12)	4 (12)	8 (17)	10 (9)
Higher degree	3 (3)	-		4 (4)
			6 (13)	
Marital status				
Single	7 (6) *	3 (9)	6 (13)	14 (12) *
Married/ co-habiting	73 (64)	20 (61)	33 (70)	69 (60)
Divorced/separated	17 (15)	4 (12)	5 (11)	14 (12)
Widowed	17 (15)	6 (18)	3 (6)	17 (15)
Ethnicity				
White	111 (97)*	32 (97)	40 (85)	109 (95)
Black – Caribbean	-	1 (3)	3 (6)	3 (3)
Black – African	-	-	1 (2)	1 (1)
Indian	2 (2)	-	1 (2)	-
Other Asian	-	-	1 (2)	-
Other	1 (1)	-	1 (2)	2 (1)

* data missing

Table 9.3: Clinical characteristics of study samples

	Head cancer patients (n=115) n (%)		Throat cancer patients (n=33) n (%)	Benign salivary gland conditions (n=47) n (%)	Non-clinical sample (n=115) n (%)
Specific site:	Tongue:	47 (41)	larynx/ glottis		N/A
	FOM:	15 (13)	33 (100)	Benign	
	Gum:	12 (10)		neoplasm of:	
	Lip:	3 (3)		Parotid gland:	
	Palate:	3 (3)		39 (83)	
	Tonsil:	7 (6)			
	Mandible:	4 (3)		Other major	
	Parotid:	2 (2)		salivary	
	Paranasal sinus:			glands:	
		3 (3)		8 (17)	
	Oropharynx:	1 (1)			
	Other mouth:	17 (15)			
	Ear:	1 (1)			
Stage: Early T1/T2	69 (60)		33 (100)	Benign	N/A
Advanced T3/T4	41 (36)*		-		
Mean time since last treated in years (SD: range)	4.6 (3.0; 1-12)		4.1** (2.4: 1-10)	4.2 (2.7; 1-10)	N/A
Type of treatment					
Surgery only (S)	46 (40)		1 (3)	47 (100)	N/A
Radiotherapy only (RT)	15 (13)		17 (52)	-	
RT & Chemotherapy (CT)	2 (1)		1 (3)	-	
S & RT	48 (42)		14 (42)	-	
S & RT & CT	4 (4)		-	-	
Major illnesses since diagnosis†					
Yes	41 (36)		20 (61)	21 (45)	29 (25)
No	74 (64)		13 (39)	26 (55)	86 (75)

* data missing

** data from 1 person missing

† or in the last 10 years for normative sample

9.5.5 Differences between samples (uni-variate analysis)

The socio-demographic and clinical characteristics of the samples are shown in Tables 9.2 and 9.3 respectively.

9.5.5.1 Socio-demographic variables

Significant socio-demographic differences were found between the four groups. Age, ($\chi^2(3)=30.10, p<0.01$), and gender ($\chi^2(3)=17.89, p<0.01$), were found to significantly differ between the samples. Post hoc comparisons showed that participants diagnosed with throat cancer (larynx/glottis) were significantly older and more likely to be male compared with the other three groups ($p<0.01$). Participants in the salivary gland conditions sample were significantly younger than the other three groups ($p<0.01$). Level of qualification differed between the normative sample and the salivary gland condition group, ($\chi^2(3)=10.10, p<0.05$), with participants in the normative sample being less qualified. The ethnic makeup of the samples also significantly differed, ($\chi^2(3)=10.15, p<0.05$), with the salivary gland group having significantly more non-white participants than the three others. There were no significant differences in marital status between groups.

9.5.5.2 Clinical variables

No significant group differences were found in terms of whether other major illnesses had been diagnosed since treatment for the condition of interest ($\chi^2(3)=6.91$, ns). However, between the three patient samples, significant clinical differences were evidenced. Significant differences in stage and treatment were found between the groups, with participants in the head cancer group being diagnosed with later stage cancers than those in the throat cancer group, $\chi^2(1)=17.12, p<0.01$ (as expected). Treatments significantly varied between the groups, as shown in Table 9.3. There were no group differences found for the amount of time (in years) since treatment.

9.5.5.3 Life Satisfaction

There were no significant differences in levels of life satisfaction between the four groups, (χ^2 (3)=1.23,ns) (Table 9.4). However, all three patient samples scored higher than the normative sample.

9.5.5.4 HR-QoL

Highly significant group differences were shown for levels of physical functioning, with differences in Physical Component Summary (PCS) scores, (χ^2 (3)=13.61,p<0.01). Post hoc comparisons demonstrated that differences were between patients having had salivary gland conditions (high PCS scores) and participants in the head cancer and normative samples (lowest PCS scores). Similarly, significant group differences were found between SF-12 subscales of: level of Physical Functioning (χ^2 (3)=10.53,p<0.05); Role Physical scores, (χ^2(3)=12.47,p<0.01); and Bodily Pain, (χ^2 (3)=12.94,p<0.01). In each case, the normative sample scored significantly lower, i.e. had worse functioning for each of the significant subscales compared to either the salivary gland condition group or the throat cancer patients (see Table 9.4 for means and medians). Patients with cancer of the head region also scored significantly worse than the salivary gland patients on subscales of Physical and Role Functioning. In contrast to these findings, significant differences in Mental Health functioning were found between the sample of salivary gland patients and those treated for head cancer, (χ^2(3)=10.34,p<0.05), however, in this case, post hoc tests revealed that the salivary gland condition sample scored significantly lower (i.e. reported worse functioning) than the head cancer patient sample.

No significant group differences were shown in Mental Component Summary (MCS) scores, (χ^2 (3)=6.71,ns), or in subscales of: General Health, (χ^2 (3)=7.10,ns); Vitality, (χ^2 (3)=4.34,ns), Social Functioning, (χ^2 (3)=4.38,ns), and Role Emotional, (χ^2 (3)=2.63,ns).

9.5.5.5 Optimism

There were no significant differences in levels of optimism between the four groups, ($\chi^2(3)=4.31$,ns).

9.5.5.6 Anxiety and depression

Differences in levels of depression were shown ($\chi^2(3)=8.45$,$p<0.05$), with differences evidenced between the normative sample and the salivary gland condition groups only. Participants in the normative sample demonstrated significantly higher levels of depression than those in the salivary gland conditions sample.

There were no significant differences in levels of anxiety between the four samples ($\chi^2(3)=2.95$,ns).

As it was revealed that there were no significant group differences between the main dependent measure of Life Satisfaction, it was decided to explore possible reasons for variation whilst controlling for effect of patient sample. Significant group differences in socio-demographic factors and HR-QoL were established previously, therefore it was imperative to determine whether these had more impact on life satisfaction than patient group alone. Two linear regression models were conducted on the whole sample, controlling for the effect of patient group (dichotomised into four dummy variables) and socio-demographic factors.

Although Satisfaction With Life Scale scores were found to be non-normally distributed, the amount of skew was within an acceptable range and the K-S statistic showed a trend towards non-significance. The score distribution is shown as a histogram (Figure 9.1).

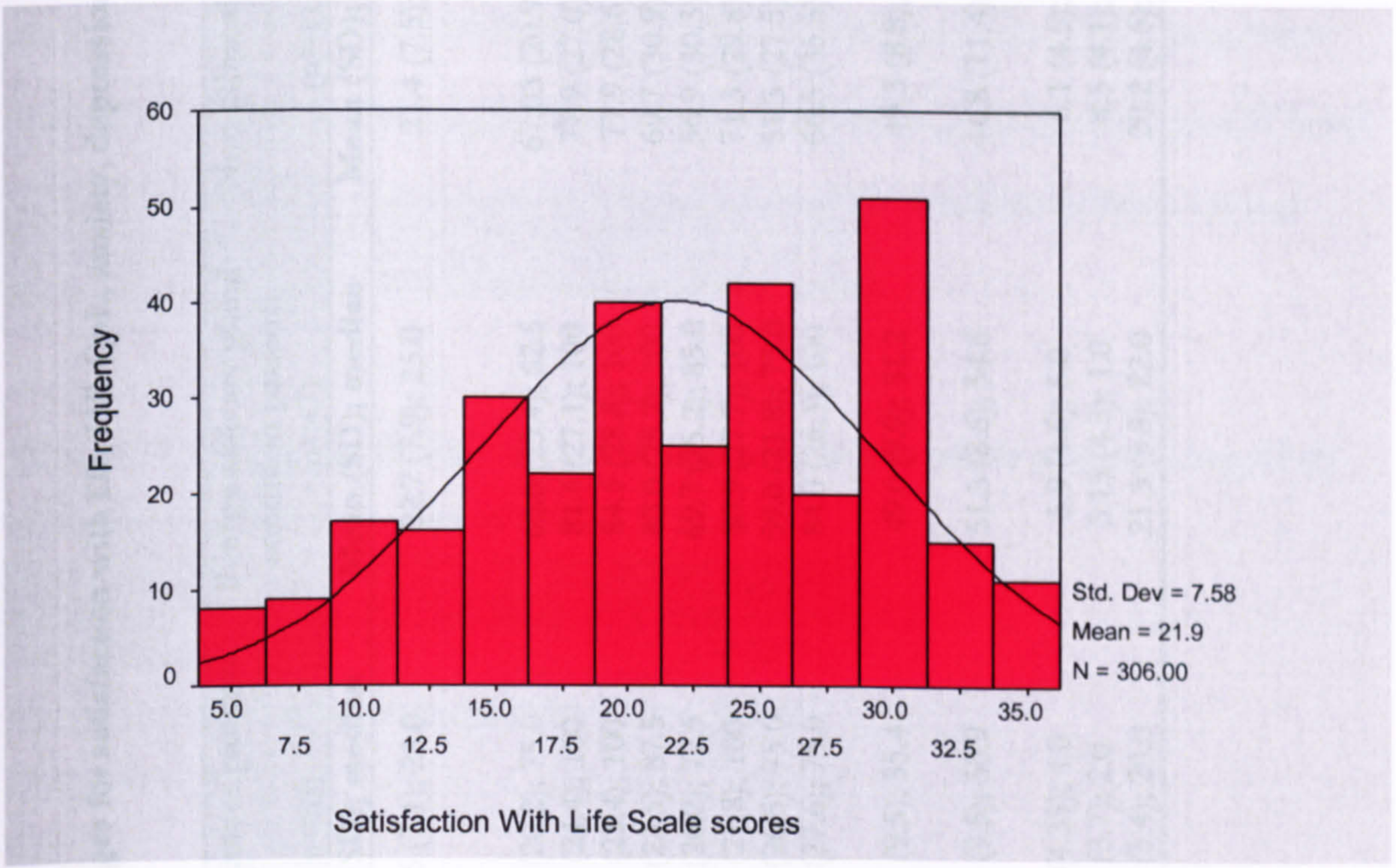


Figure 9.1: Histogram of Satisfaction With Life Scale (SWLS) scores for combined sample (n=306)

9.5.6 Determinants of Satisfaction with Life (SWL)

9.5.6.1 Model 1: Using SF-12 PCS and MCS scores

All variables were entered into the first model using a stepwise method (i.e. age, gender, marital status, qualifications, ethnicity, sample group, time since treatment, diagnosis of major illness since treatment, optimism, anxiety, depression and HR-QoL. HR-QoL was represented by the component summary scores of MCS and PCS. All variables could be entered without reducing the power of the study as the overall sample size was large (approx. 300).

Table 9.4: Internal consistency, means, standard deviations (SD), medians and ranges for satisfaction with life, HR-QoL, anxiety, depression and optimism scores

	Cronbach's α	Head cancer patients (n=115)	Throat cancer patients (n=33)	Benign salivary gland condition patients (n=47)	Non-clinical sample (n=115)
		Mean (SD); median	**Mean (SD); median**	**Mean (SD); median**	**Mean (SD); median**
Satisfaction with Life Scale (SWLS):	0.89 (n=306)	21.9 (7.7); 23.0	22.16 (7.1); 23.0	22.7 (7.9); 25.0	21.4 (7.5); 21.0
SF-12v2 Domain					
Mental Health	0.64 (n=307)	73.4 (22.1); 75.0	73.5 (20.2); 75.0	63.6 (23.4); 62.5	67.03 (20.9); 75.0
Role Emotional	0.91 (n=307)	78.3 (25.0); 87.5	82.2 (24.4); 100	81.6 (27.1); 100	77.9 (27.0); 87.5
Social Functioning‡ *	n/a	76.5 (29.9); 100	82.6 (25.4); 100	84.6 (28.8); 100	77.9 (28.6); 100
Role Physical	0.92 (n=308)	67.4 (29.2); 75.0	75.8 (23.5); 87.5	83.0 (25.2); 100	69.7 (30.9); 75.0
General Health‡	n/a	64.0 (26.7); 60.0	64.5 (26.2); 72.5	69.7 (25.2); 85.0	56.9 (30.3); 60.0
Bodily Pain‡	n/a	80.3 (26.0); 100	87.1 (21.8); 100	80.9 (27.7); 100	71.3 (29.8); 75.0
Vitality‡	n/a	57.3 (24.7); 50.0	56.1 (26.5); 75.0	59.0 (21.8); 75.0	51.3 (27.5); 50.0
Physical Functioning*	0.84 (n=309)	67.2 (35.3); 75.0	75.8 (27.6); 75.0	84.0 (26.3); 100	66.5 (35.5); 75.0
Mental Component Summary (MCS) score‡*	n/a	50.8 (10.0); 53.3	52.8 (9.5); 55.4	49.0 (9.9); 51.2	49.3 (8.8); 50.7
Physical Component Summary (PCS) score‡*	n/a	45.6 (11.5); 49.0	48.5 (9.5); 50.9	51.5 (8.6); 54.6	44.8 (11.4); 47.1
HADS subscale:					
Anxiety	0.87 (n=306)	5.1 (4.1); 5.0	5.5 (4.35); 4.0	5.9 (4.6); 5.0	6.1 (4.5); 5.0
Depression	0.87 (n=308)	4.0 (3.9); 3.0	4.0 (3.7); 2.0	3.13 (4.3); 1.0	4.5 (4.1); 3.0
LOT-R	0.81 (n=306)	21.4 (5.4); 22.0	20.2 (5.4); 20.0	21.3 (5.8); 22.0	20.2 (4.6); 20.0

‡Cronbach's alpha cannot be computed.

* data missing

Analysis revealed that optimism explained the largest amount of variance in life satisfaction, along with levels of depression, levels of Mental and Physical HR-QoL (PCS and MCS), marital status and age (*adj.* R^2 *=0.47; F=44.05; df=6,286;p<0.05)*. Higher levels of optimism, better physical and mental functioning, being married (or living with a partner) older age, and lower levels of depression were associated with higher levels of life satisfaction (Table 9.5) and altogether could explain 47% of the variance in SWL score.

Table 9.5: Explanatory factors of Satisfaction with Life in whole sample using SF-12 component summary scores (n=293)

Explanatory factor	Std β
Optimism (LOT-R)	0.32**
Mental Component Summary (SF-12)	0.23**
Depression	-0.19*
Age	0.14**
Marital status	0.13**
Physical Component Summary (SF-12)	0.13*

Overall Model: R^2 =0.48; adj. R^2 =0.47; F=44.05; df=6,286*

*p<0.05, **p<0.005

9.5.6.2 Model 2: Using SF-12 subscales

The second multiple regression model was again conducted with SWL as the outcome variable, and including explanatory factors as described previously, however the eight subscales of the SF-12 were entered instead of the two summary component scores. This was to explore in more detail whether particular elements of HR-QoL were important when making judgements of life satisfaction.

Using more specific measures of HR-QoL, it was found that higher levels of optimism, lower levels of depression, better Role Emotional functioning, older age and being married (or living with a partner), were associated with higher levels of SWL (Table 9.6) and could explain

approximately 48% of the variance in life satisfaction scores (*R^2 =0.49; adj. R^2 =0.48; F=57.65; df=5,297; p<0.01).*

Table 9.6: Explanatory factors of Satisfaction with Life in whole sample using SF-12 subscales (n=303)

Explanatory factor	Std β
Optimism (LOT-R)	0.34**
Depression	-0.30**
Role Emotional Functioning (SF-12)	0.17**
Age	0.15**
Marital Status	0.11*

Overall Model: R^2 =0.49; adj. R^2 =0.48; F=57.65; df=5,297*

*p<0.01; **p<0.005

Tests for normality, linearity, homoscedasticity, multicollinearity and independence of residuals

For each of the models 1and 2, plots of standardised residuals against standardised predicted values were fairly random and evenly dispersed, therefore, data were probably within the limits for meeting assumptions of homoscedasticity and linearity. Assumptions were met for normally distributed errors. The P-P plots of normally distributed residuals represented normal distributions and histograms of standardised residuals also demonstrated normal distributions. The assumption of independent errors was met with Durbin-Watson statistics of approximately 1.9. Collinearity statistics of tolerance and variance inflation factors (VIF) were well within acceptable ranges (>0.2 and <10 respectively) indicating that the assumptions of no multicollinearity were met.

9.5.7 Relationships between cognitive adaptation (represented by SWL), time since treatment and clinical factors

In order to explore whether time since treatment and type of treatment impacted on adaptation and to *further* test the hypothesis 1: *'Controlling for time since treatment, patients treated for cancer of the head will show cognitive adaptation by demonstrating similar levels of life satisfaction as:*

a) Patients treated with surgery for a benign condition of the head,

b) Patients treated for early stage laryngeal cancer'.

Further analyses were conducted using the three patient samples only (head cancer, throat cancer and salivary gland patients).

9.5.7.1 Correlational analysis

Correlation analysis with all explanatory variables and SWL were conducted. Socio-demographic variables of age ($r=0.15;p<0.05$) and marital status ($r=0.18;p<0.05$), clinical variables of stage of cancer ($r=-0.19;p<0.05$), and treatment group of surgery only ($r=0.15;p<0.05$), depression ($r=-0.60;p<0.01$), anxiety ($r=-0.44;p<0.01$), optimism ($r=0.54;p<0.01$) and all HR-QoL sub-scales ($p<0.01$) were significantly associated with satisfaction with life. Time since treatment was not significantly associated with satisfaction with life ($r=-0.03;p>0.05$) or depression ($r=-0.04;p>0.05$).

9.5.7.2 Regressional analysis

As there were only 195 patients included in this analysis, stepwise regression analysis was conducted using only variables which proved significantly associated with SWL in univariate analysis.

Table 9.7: Explanatory factors of Satisfaction with Life in patient groups only (n=195)

Explanatory factor	Std β
Optimism (LOT-R)	0.33**
Depression	-0.31**
Role Emotional Functioning (SF-12)	0.19*
Age	0.19**

Overall Model: R^2 =0.49; adj. R^2 =0.48; F=44.19; df=4,186*

*p<0.01; **p<0.005

None of the clinical factors such as treatment type, or stage of cancer could significantly explain satisfaction with life, and again, optimism and levels of depression contributed the most (Table 9.7). Together with age and role emotional functioning, this model could explain approximately 48% of the variance in life satisfaction amongst this mixed patient sample (*R^2 =0.49; adj. R^2 =0.48; F=44.19; df=4,186; p<0.01).*

Tests for normality, linearity, homoscedasticity, multicollinearity and independence of residuals

Plots demonstrated that there may have been heteroscedasticity in the data from the regression model. Assumptions were met for normally distributed errors. The p-p plot of residuals appeared slightly deviated from the normal distribution and the histogram of standardised residuals demonstrated a slightly positively skewed distribution. The assumption of independent errors was met with a Durbin-Watson statistic of 2.0. Collinearity statistics of Tolerance and VIF were well within acceptable ranges indicating that the assumptions of no multicollinearity were met. In conclusion, the results presented in Table 9.7 should be interpreted with a certain amount of caution.

9.5.8 Sample differences in health status (HR-QoL)

The results of uni-variate analyses (and Table 9.4) indicated that there were noticeable differences in HR-QoL between the samples. Two regression models were constructed for each of the HR-QoL summary component scales of PCS and MCS, to assess how much of the variance was due to patient group or socio-demographic differences between the samples. The second null hypothesis was tested:

There will be no significant differences in levels of HR-QoL between patients with head cancer and, a) Patients treated with surgery for a benign condition of the head; b) Patients treated for early stage laryngeal cancer; c) An age and gender matched non-clinical sample.

Previous uni-variate analysis demonstrated no group differences in Mental Component Summary scores (MCS) and thus regression analysis failed to find any variance due to sample group. The only socio-demographic factor to significantly contribute to MCS score was gender *(R^2 =0.05; adj. R^2 =0.04; F=14.7; df=1,295;n=297; p<0.001)*. The association was negative indicating that being female was associated with reporting lower MCS scores. Although found to be significant, gender only contributed 4% of the variance in MCS.

Regarding physical health status, analysis revealed that age and being in a particular sample group significantly contributed to the variance in Physical Component Summary (PCS) scores *(R^2 =0.14; adj. R^2 =0.13; F=23.4; df=2,299;n=302; p<0.001)*. Both factors were negatively associated with PCS score indicating that increasing age, and being in the normal sample group were associated with lower physical HR-QoL.

Tests of the models revealed that there might have been heteroscedasticity in the data. Assumptions were met for normally distributed errors. The p-p plots of residuals looked slightly deviated from the normal distribution and the histograms of standardised residuals demonstrated slightly positively skewed distributions for both models. The assumption of

independent errors was met for both models. Collinearity statistics of Tolerance and VIF were well within acceptable ranges indicating that the assumptions of no multicollinearity were met. In conclusion, the results from the two models examining the explanatory factors for MCS and PCS scores should be interpreted with a certain amount of caution.

9.5.9 Adaptation in patients treated for cancer of the head region

This study also sought to investigate adaptation issues in the main sample of patients only, by firstly assessing whether time since treatment affected perceptions of life satisfaction, and secondly, whether levels of depression and anxiety differed from the age and gender matched non-clinical sample. The following null hypotheses were tested:

'Time since treatment will not be associated with levels of life satisfaction in head cancer patients'.

'Patients treated for cancer of the head will show emotional adaptation by demonstrating significantly similar levels of depression and anxiety to that of the age and gender matched non-clinical sample.'

Although there were no statistically significant differences in life satisfaction scores between the samples, the mean score for the head cancer sample was higher than that for the age and gender matched non-clinical sample (Table 9.4).

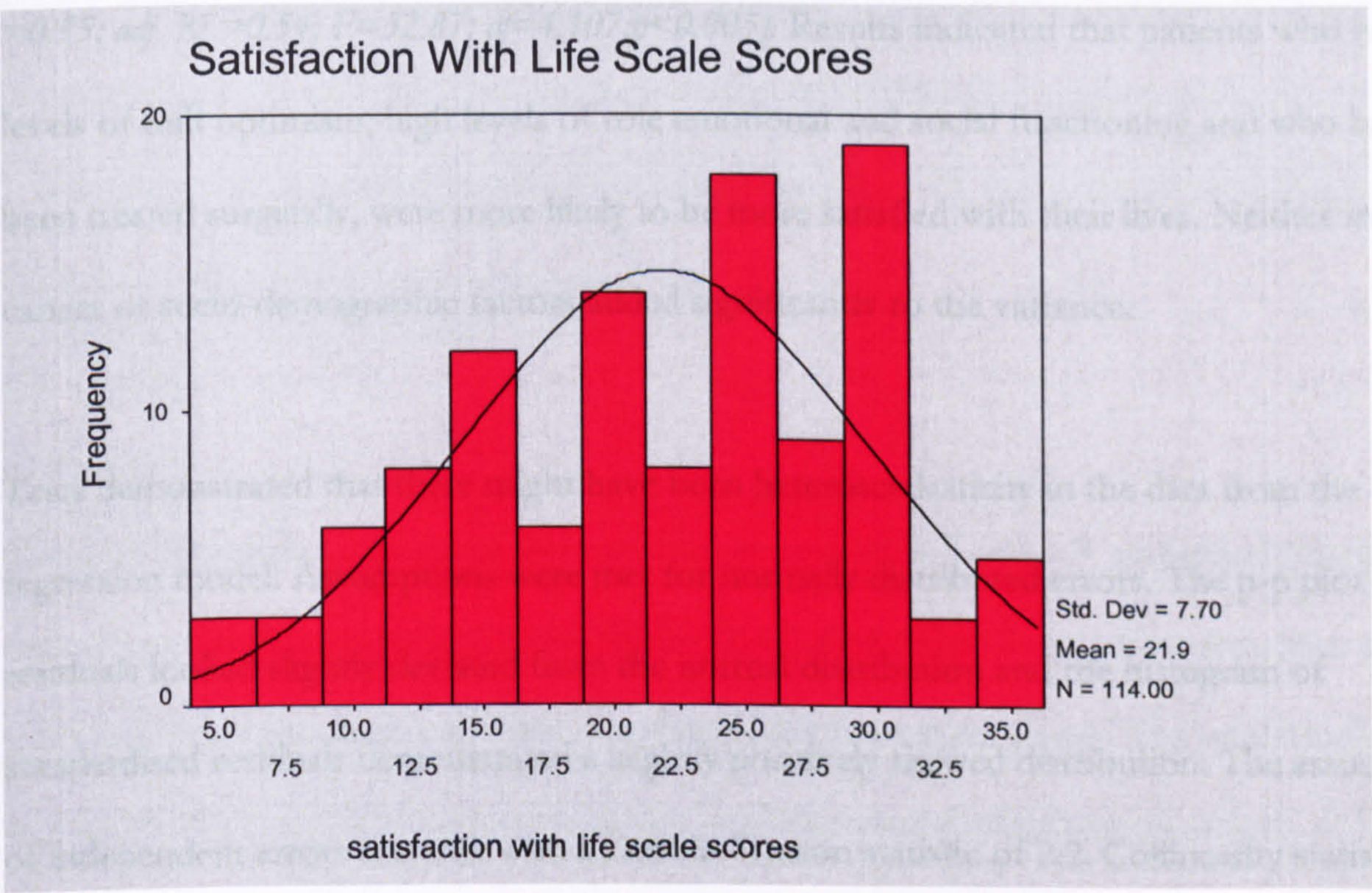


Figure 9.2: Histogram of Satisfaction With Life Scale (SWLS) scores for patients treated for head cancer (n=114)

9.5.9.1 Correlational analysis

Correlation analysis with explanatory variables and satisfaction with life were conducted using head cancer patients only. The socio-demographic variable of age ($r=0.19;p<0.05$), clinical variables of stage of cancer ($r=-0.22;p<0.05$), and treatment group of surgery only ($r=0.26;p<0.01$), depression ($r=-0.57;p<0.01$), anxiety ($r=-0.42;p<0.01$), optimism ($r=0.59;p<0.01$) and all HR-QoL sub-scales ($p<0.01$) were significantly associated with satisfaction with life. Time since treatment was not significantly associated with satisfaction with life ($r=0.03;p>0.05$) or depression ($r=-0.08;p>0.05$).

9.5.9.2 Regressional analysis

Multivariate analysis revealed that only four factors significantly contributed to variation in SWL scores in the head cancer patients (Table 9.8). Similar to previous results, optimism was positively associated with SWL, along with aspects of HR-QoL and type of treatment ($R^2 = 0.55$; *adj.* $R^2 = 0.54$; $F=32.87$; $df=4,107;p<0.005$). Results indicated that patients who had high levels of trait optimism, high levels of role emotional and social functioning and who had only been treated surgically, were more likely to be more satisfied with their lives. Neither stage of cancer or socio-demographic factors added significantly to the variance.

Tests demonstrated that there might have been heteroscedasticity in the data from the regression model. Assumptions were met for normally distributed errors. The p-p plot of residuals looked slightly deviated from the normal distribution and the histogram of standardised residuals demonstrated a slightly positively skewed distribution. The assumption of independent errors was met with a Durbin-Watson statistic of 2.2. Collinearity statistics of Tolerance and VIF were well within acceptable ranges indicating that the assumptions of no multicollinearity were met. In conclusion, the results from the analysis presented in Table 9.8 should be interpreted with some caution.

Table 9.8: Explanatory factors of Satisfaction with Life in patients with cancer of the head only (n=114)

Explanatory factor	Std β
Optimism (LOT-R)	0.46**
Role Emotional Functioning (SF-12)	0.26**
Surgery only	0.20**
Social Functioning	0.19*
Overall Model: R^2 =0.55; adj. R^2 =0.54; F=32.87; df=4,107**	

*p<0.05; **p<0.005

In contrast to the previous models, depression did not significantly contribute to life satisfaction in this patient sample, and as SWL is intended to assess the cognitive rather than affective components of satisfaction, a further question was asked, relating to what factors could explain affective aspects of SWL (i.e. depression).

9.5.9.3 What factors contribute to emotional adaptation (i.e. levels of depression and anxiety)?

Further regression analyses were conducted using depression and anxiety as outcome variables. It was further hypothesised that levels of functioning (i.e. HR-QoL) would be associated with both depression and anxiety.

Depression

The overall model consisting of five variables, presented in Table 9.9, accounted for 70% of the variance in depression (*adj. R^2 =0.70; F=52.37; df=5,107;p<0.005)*. Four subscales of HR-QoL, and optimism were negatively associated with depression scores. The model indicated that as HR-QoL and levels of optimism lowered, depressive symptoms increased.

Table 9.9: Explanatory factors of depression in patients with cancer of the head only (n=113)

Explanatory factor	Std β
Role Physical	-0.28**
Mental Health	-0.28**
LOT-R	-0.23**
Social Functioning	-0.21*
General Health	-0.17*

Overall Model: R^2 =0.71; adj. R^2 =0.70; F=52.37; df=5,107**

*p<0.05; **p<0.005

Anxiety

Anxiety was accounted for (59% of the variance) by levels of optimism and mental health (*adj. R^2 =0.59; F=77.96; df=2,110 ;p<0.001)*. The model (Table 9.10) indicated that high levels of anxiety were related to low levels of optimism and low levels of mental health.

Table 9.10: Explanatory factors of anxiety in patients with cancer of the head only (n=112)

Explanatory factor	Std β
Mental Health	-0.68**
LOT-R	-0.15*

Overall Model: R^2 =0.59; adj. R^2 =0.58; F=77.96; df=2,110**

*p<0.05; **p<0.001

Tests demonstrated that there might have been heteroscedasticity in the data from each of the regression models. Assumptions were met for normally distributed errors. The p-p plots of residuals looked slightly deviated from the normal distribution and histograms of standardised residuals demonstrated slightly negatively skewed distributions. The assumption of independent errors was met with Durbin-Watson statistics of approximately 2.0. Collinearity

statistics of Tolerance and VIF were well within acceptable ranges indicating that the assumptions of no multicollinearity were met. In conclusion, the results from multi-variate analyses examining the explanatory factors of depression and anxiety should be interpreted with a certain amount of caution.

9.5.9.4 Comparison of levels of anxiety and depression between patients with cancer of the head, the age and gender matched non-clinical sample and a normative sample

There was some concern over whether our age and gender matched non-clinical sample was representative of a normal population, as scores of physical functioning and pain were found to be significantly worse for this sample than our patient samples. Moreover, levels of depression and anxiety appeared to be higher than all three patient samples and significantly higher than the benign salivary gland patients.

Unfortunately there are no widely used population data for the HADS, with which to compare our normative sample, however, recent data have been published for a large non-clinical adult UK sample (Crawford, Henry, Crombie, & Taylor, 2001). In order to ascertain whether the patients treated for head cancer had comparable levels of depression and anxiety to the normal population (i.e. demonstrating emotional adaptation post-treatment), a comparison was made between our main head cancer sample, the age and gender matched non-clinical sample and the normative data set. Table 9.11 presents descriptive data for the three data sets.

The HADS raw scores were positively skewed for all samples. The head cancer sample displayed lower levels of anxiety than both of the normative samples. Similarly, lower percentages of the sample, compared to the normative data sets, could be classed as having moderate or severe levels of clinical anxiety. The two normal samples demonstrated similar mean values, however, our matched sample had a slightly lower median value. Similar

proportions of both samples had scores of 8 or more, which signified clinical caseness (32% and 33%), although the distribution of scores across the three clinical divisions varied.

Regarding scores on the depression subscale, all three samples displayed the same median value of 3, which was lower than the anxiety scores. The use of mean and SD values are limited with skewed data, however, scores across the samples were similar, albeit lowest in the adult UK normative sample and highest in our age and gender matched non-clinical sample. This may have been due to the differences in sample size. Examining the proportions of participants falling within the limits for clinical depression, the matched non-clinical sample had the highest proportion (21%), followed by the head cancer sample (17%) and then the adult UK normative sample (11%).

Due to the fact that a substantial proportion of the general adult population endorsed a number of anxiety and depression items, Crawford and colleagues (2001) argue for the use of a cut-off of 10/11 to signify a clinical case instead of the recommended 8 (Zigmond et al., 1983).

Data for gender is not available for the adult UK normative sample, however, the authors report that females scored significantly higher than males on both scales. The results from the comparisons between the two normative data sets demonstrate that the age and gender matched community sample collected from the market research agency was not representative of the normal population, particularly in terms of levels of depression. This may have been due to the relatively small sample size or data collection methods. Any comparisons based on this sample should be interpreted cautiously.

Table 9.11: Comparison of HADS scores between head cancer sample, matched non-clinical sample and adult UK normative data

	Head cancer sample (n=114)		Matched non-clinical sample (n=115)		Adult UK normative data (n=1792)	
	Anxiety	**Depression**	**Anxiety**	**Depression**	**Anxiety**	**Depression**
Mean (SD)	5.1 (4.1)	4.0 (3.9)	6.1 (4.5)	4.5 (4.1)	6.1 (3.8)	3.7 (3.1)
Median	5.0	3.0	5.0	3.0	6.0	3.0
	n (%)	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Mild clinical case (scores of 8-10)	18 (16.2)	9 (7.9)	16 (14.4)	13 (11.7)	362 (20.6)	140 (7.8)
Moderate clinical case (scores of 11-15)	6 (5.4)	10 (8.8)	15 (13.5)	8 (7.2)	179 (10.0)	52 (2.9)
Severe clinical case (scores of ≥16)	3 (2.7)	0 (0)	5 (4.5)	2 (1.8)	36 (2.6)	13 (0.7)

9.6 DISCUSSION

The primary aims of this chapter were to assess the extent to which patients diagnosed with cancer of the head region showed cognitive and emotional adaptation after treatment. In order to do this, levels of life satisfaction and anxiety and depression were examined, in relation to an age and gender matched non-clinical sample and two additional patient groups.

9.6.1 Cognitive adaptation

Preliminary results showed that levels of satisfaction with life (SWL) reported by the head cancer patients were not significantly different from the non-clinical sample or patients who had been treated for an early stage throat cancer or a benign salivary gland condition. Therefore, the first hypotheses were accepted. Moreover, mean values demonstrated that all patient samples reported higher levels of life satisfaction than the non-patient sample (although this did not reach statistical significance). This finding is comparable to previous studies of SWL in which no differences in life satisfaction have been demonstrated between different patient groups and healthy controls (Kreitler, Chaitchik, Rapoport, Kreitler, & Algor, 1993).

However, a Norwegian study of 204 long term HNC survivors (7-11 years since diagnosis) and 766 matched controls, reported significantly worse levels of life satisfaction and physical health between their patient sample and a matched healthy sample (Bjordal, Mastekaasa, & Kaasa, 1995). The authors explain the lack of consistency between these results and that of the cancer literature (Danoff, Kramer, Irwin, & Gottlieb, 1983; Kaasa, Aass, Mastekaasa, Lund, & Fossa, 1991; Kreitler et al., 1993; Olweny, Juttner, & Rofe, 1993) by hypothesising that re-appraisal and other processes of adaptation *'may not be applicable for a population with considerable side-effects, including physical limitations and changes of appearance after treatment, which are constant reminders of their disease'* (Bjordal et al., 1995). Other research has indicated that life satisfaction in HNC patients is related to pain, speech difficulties and dysphagia (Morton, 1995). Our results suggest, however, that despite worse physical HR-QoL reported by the head cancer sample, compared

to patients in the non-cancer patient group (salivary gland conditions), levels of life satisfaction were similar. This demonstrates that physical limitations do not necessarily lead to worse perceptions of life satisfaction.

Despite finding no significant differences in HR-QoL between the head cancer sample and the non-clinical matched sample, examination of mean values indicated that the head cancer sample scored lower than all other patient samples on six of the eight HR-QoL domains (including the PCS score). Thus, hypothesis 2a was rejected and hypotheses 2b and c were accepted as no significant differences in physical HR-QoL were found between the head cancer patients and the normative sample or throat cancer sample.

Multivariate analysis demonstrated that SF-12 domains, in particular Role Emotional Functioning were contributory factors to SWL in all of the samples combined, and in the head cancer sample only. In the whole sample combined (n=303), approximately half of the variance in SWL (adjusted R^2 of 0.48) could be accounted for by levels of optimism, depression, role emotional functioning, age and marital status. Interestingly, low levels of depression and high levels of optimism were both independent explanatory factors of high life satisfaction indicating that these are distinct and independent factors not just opposite ends of the same spectrum. Being married was also associated with high levels of life satisfaction which is also robustly demonstrated in the literature (Waite, 1995). The relationship between marital status and SWB has been hypothesised in two ways. Firstly, the 'selection' hypothesis, that satisfaction with life leads to more success with marrying (Mastekaasa, 1992), and secondly, the 'social role' explanation that marriage itself predisposes to more opportunity for social support which leads to higher levels of life satisfaction (Johnson & Wu, 2002).

Few studies have been published reporting the levels of life satisfaction in HNC patients, indeed fewer still have assessed the patterns of life satisfaction over a longer period of time. It

was hypothesised that time would have an effect on levels of cognitive and emotional adaptation for many reasons, not least in terms of healing after treatment and diminishing levels of pain, however, we failed to find any effect of time on levels of life satisfaction or emotional adaptation, and therefore, hypothesis 3 was accepted.

Treatment modality aside, no other clinical or treatment related factors were related to SWL. Having had 'surgery only' was found to be protective of SWL which may have been due to the length of time taken to heal, as opposed to the long term effects of radiotherapy. Alternatively, 'surgery only' may have been acting as a surrogate marker for tumour size or tumour severity as larger tumours are more likely to be treated with multiple modes of treatment. However, analysis with stage data was not found to be significant. No other stage related data was available.

Although our study data were only cross-sectional, and thus can not indicate whether life satisfaction had changed over time, previous studies have reported that life satisfaction (as measured by the Life Satisfaction (LS) Scale (Warr et al., 1979)) undergoes significant improvement between diagnosis and 12 months later (Morton, 1995; Morton, 2003). It is plausible to assume that life satisfaction decreases around the time of diagnosis and treatment and therefore any subsequent increase could be taken as an indicator of cognitive adaptation.

9.6.2 Emotional adaptation

Levels of depression and anxiety in all of the samples were low (although lowest for depression) and well under boundaries for possible clinical disorders (Zigmond et al., 1983). There were no significant differences in anxiety and depression levels between the head cancer sample and the comparison samples, and therefore null hypothesis four was accepted.

HR-QoL and optimism, explained 70% of the variance in depression and 58% of the variance in anxiety in the head cancer sample only. As levels of HR-QoL and optimism lowered, depression and anxiety increased. These data indicate that patients that are at risk of long term depression and anxiety are those that have worse HR-QoL and lower levels of dispositional optimism. Both of these factors could be assessed at baseline and shortly after treatment which potentially has implications for early intervention. Although longitudinal assessment did not involve the same patient sample as previous chapters, mean values for both anxiety and depression in the current study indicate that levels may continue to decrease over time.

Time since treatment, and the majority of the clinical and treatment related factors (surgery aside) had no influence on either cognitive or emotional adaptation, thereby providing further support for the premise that adaptation is a stable, personality based trait.

The cognitive and affective components of SWB have been reported as highly interrelated (Diener, Suh, & Oishi, 1997), and depression was consistently found in the present study to be an explanatory factor of life-satisfaction, however, anxiety was not.

9.6.3 The role of optimism in adaptation

Research has shown that demographic factors such as health, income, educational background and marital status only account for a small amount of variance in SWB. Instead, studies have shown that SWB is fairly stable over time, that it may rebound with major life-events and that it is often correlated with personality traits (Diener, Oishi, & Lucas, 2003).

Several meta-analyses have been conducted of the many personality traits that have been researched in association with aspects of SWB (DeNeve & Cooper, 1998; Lucas & Fujita, 2000), however, much of this research has focused on the correlations between SWB and extraversion and neuroticism (Costa & McCrae, 1980; Watson & Clark, 1992). The strong

correlations found between negative affect and neuroticism, extraversion and pleasant affect, have lead many researchers to suggest that these traits provide the primary links between personality and SWB. However, as the review by DeNeve & Cooper (1998) demonstrated, other personality dimensions and traits, such as self-esteem and dispositional optimism, are also consistently related to SWB (Lucas, Diener, & Suh, 1996). Little is known as to whether these traits remain predictive once extraversion and neuroticism are controlled for.

As previously highlighted, the head cancer sample in this study demonstrated similar levels of life satisfaction as the other samples, despite reporting worse HR-QoL. Personality traits such as dispositional optimism could potentially confound the interpretation of these results. At first glance, it could be considered that cognitive adaptation has occurred despite long lasting physical difficulties. However, levels of optimism were found to be highest in the head cancer sample (although not significantly), which may suggest that elevated life satisfaction scores could be a result of an optimistic outlook.

Indeed multivariate analyses demonstrated that the most important determinant of cognitive adaptation throughout the analyses was level of optimism and this also held true with analyses with the head cancer sample alone. A previous similar study involving 55 HNC patients, and comparison samples comprising orthopaedic patients and healthy controls, found that SWL was not correlated with optimism (or health) in the HNC sample but was strongly associated with optimism in the other two samples (Kreitler et al., 1993). The authors speculate that life satisfaction in cancer patients is denoted by satisfaction with other areas apart from health and optimism and this may be a function of seeking support from a wide variety of other sources, such as work, family and social life. The present study, demonstrates that cancer patients maintain similar levels of SWL and that optimism is a large explanatory factor.

9.6.4 Theories of adaptation

The current study did not attempt to examine the underlying processes of adaptation and subjective well-being, however, several theoretical approaches aside from Leventhal's self-regulatory theory (1980) have been posited.

Telic theorists hypothesize that SWB is gained when goals and needs are achieved (Diener, 1984). Therefore, the determinants of SWB are not global but differ according to people's values and goals. According to goal theory, if people perceive themselves to have made progress towards their goals, in accordance to their values, then they are likely to be satisfied. For example, studies have demonstrated that individuals high in SWB (and low in negative affect) perceived their goals to be more important and the probability of success higher than those low in SWB (Emmons, 1986), whereas those low in SWB (and high in negative affect) perceived more conflict between their goals (Emmons & King, 1988). In addition, Carver and Scheier (1990) proposed that perceptions of progression towards goals at a faster rate than standard leads to positive affect, whereas progress at a slower rate leads to negative affect. Consistent with this hypothesis, research by Brunstein (1993) found that perceived progress towards goals caused positive changes in SWB rather than vice versa (Brunstein, 1993). Thus, SWB, in particular life-satisfaction, is likely to reflect the individual's fulfilment of their values and goals, which also involves the search for meaningfulness in one's life, especially after a life-threatening illness. In this way, SWB could be considered a more robust measure of QoL, because it reflects deeper values beyond hedonistic pleasure and transient emotion.

Another theoretical explanation as to why people who are confronted with a serious health threat demonstrate levels of well-being comparable to the normal population, is provided by theories of cognitive adaptation. For example, Taylor's theory of cognitive adaptation suggests that people may use a number of cognitive strategies to counteract the negative impact of distress on well-being. Taylor argues that when an individual experiences a personally

threatening event, the readjustment process focuses around three themes: a search for meaning in the experience, an attempt to regain mastery over the particular event and life in general, and an effort to restore one's self-esteem (Taylor, 1983). Research has demonstrated that patients who were successful across these three themes, were emotionally better adjusted than those who were unable to form and maintain this set of illusions or perceptions (Taylor, Lichtman, & Wood, 1984). The majority of research based on Taylor's theory of cognitive adaptation has focused on the assessment of optimism, control and self-esteem to represent the theory's three components. These aspects have been positively related to adaptation in a number of different patient groups, including coronary heart disease and cancer (Helgeson, 1999; Stiegelis *et al.*, 2003).

Studies involving healthy reference groups provide additional support for this theory. Patients have been found to demonstrate similar levels of optimism, control and self-esteem as healthy samples, which would indicate success in maintaining positive cognitions and thus adaptation to a health threat (Carpenter, 1997; Stiegelis *et al.*, 2003). It is also equally plausible that in order to adapt to the health threat, some form of 'response-shift' (see chapter 3) has occurred over time, leading to reprioritisation of goals.

9.6.5 Limitations

A major limitation with this study was with the age and gender matched non-clinical sample. This sample was collected for use as a comparison sample and was intended to represent a sample derived from the normal population. However, it was quite apparent from the data that it was not representative of a 'normative' sample. Standardised scores on the HR-QoL measures demonstrated that scores were lower than all of the patient groups for; role emotional functioning; general health; bodily pain; vitality and physical functioning which could not be explained by differences in age or gender. MCS and PCS scores were also demonstrably lower than the patient samples, and standardised levels (which may be explained by age related

factors, as summary scores are not age and gender standardised). In addition, the non-clinical sample displayed more elevated levels of depression than the adult UK normative data set (although depression scores were probably not significantly different). This lead to the unfortunate conclusion that the 'normative sample' was not representative of the normal population and thus any comparisons using this group have to be treated with caution. This finding was surpising as a reputable research agency supplied the data, however it is not known from where they sampled. It is also equally plausible that the clinical samples were also highly selected, i.e. those that were worse off in terms of HR-QoL or anxiety and depression did not participate. This responder bias would have lead to an even larger discrepancy between the relatively well clinical samples and the unrepresentative normative sample.

Despite the acknowledgment that adaptation is a dynamic process, few studies, including the present study, have attempted to examine the dynamic nature of its occurrence. Instead most of the evidence for adaptation is derived from cross-sectional studies (Frederick & Loewenstein, 1999). The main limitation of not using longitudinal data is that it prevents the comparison of post-event levels of SWL with their pre-treatment (or pre-diagnosis) levels, thereby limiting the evidence it can give for adaptation occurring. The use of comparison groups, using a mixture of benign and malignant tumour patient samples and a normative sample were justified in order to provide information on other peoples levels of life SWB, with and without having undergone a life-threatening event. In addition, the cross-sectional design does not provide information on the direction of causation, which may be more pertinent to relationships with factors such as marital status and levels of depression.

It may have been fruitful to collect more information on the possible underlying processes of adaptation by including a measure of illness perceptions in the patient samples. However, it was felt that at this preliminary stage in the research into SWB, it would be more appropriate to keep the questionnaire pack as minimal as possible to increase the response rates. Further

research could utilise the knowledge gained from the previous studies presented in chapters 4 and 6-8, to study in more depth possible underlying factors in addition to personality traits.

Scores of the Satisfaction With Life Scale (SWLS) can be interpreted in terms of absolute life satisfaction as well as relative life satisfaction. A score of 20 represents the neutral point on the scale, the point at which the respondent is about equally satisfied and dissatisfied. The authors suggest that scores between 21 and 25 represent slightly satisfied, with 26 and over representing satisfied. Scores between 15 and 19 represent slightly dissatisfied with life and scores lower than 15 represent the spectrum from very to extremely dissatisfied. The samples in the present study, demonstrate satisfaction levels that would be deemed by the authors as 'slightly satisfied'. Compared to the mean values presented as 'normative data' in a review of studies using the SWLS (Pavot et al., 1993), twenty-one of thirty-five of the mean values presented were higher than our highest mean value of SWL (benign salivary gland condition patients). Although it appears that our patient samples have relatively high levels of satisfaction, populations reporting lower levels of satisfaction with life than our samples were; male prison inmates, hospital inpatients treated for alcohol abuse and abused women (Pavot et al., 1993). It is not known why all our samples, in particular the 'normative sample' did not score higher with respect to life satisfaction and HR-QoL, it would be interesting to compare these data with UK standardised data.

9.6.6 Implications for further research

Assessing SWB (cognitive and emotional adaptation) appears to be promising for use in clinical practice and may provide additional information to standard HR-QoL measures. Our mixed samples demonstrated that positive cognitions may be reported in patients irrespective of severity of illness. To understand which individuals are able to cognitively and emotionally adapt after a threatening event such as cancer, further research should examine individual differences in positive cognitions. Intervening in those patients who do not show signs of

adapting could be valuable in enhancing their satisfaction with life and reducing psychological distress. Possible interventions could include one to one counselling or cognitive behavioural therapy to decrease levels of depression and increase opportunity for seeking social support.

As previously mentioned, another avenue of research would be to build on this study by examining the process variables underlying adaptation. This could be achieved using a longitudinal study design guided by either Taylor's theory of cognitive adaptation (Taylor, 1983) or Leventhal's SRM (Leventhal et al., 1984). This would provide data on the dynamic process of adaptation and would provide more information on the relationship between cognitive and emotional adaptation and whether they occur in parallel.

9.6.7 Conclusions

Similar to the majority of other cross-sectional studies of life satisfaction and long term emotional outcomes, the present study found that objective circumstances accounted for little variance in reports of subjective well-being (SWB).

Survivors of cancer of the head region reported similar levels of satisfaction with life as the normal population, therefore there is evidence that patients with HNC cognitively and emotionally adapt over time. This lends support to the premise that people's well-being is relatively stable and, over time, people adapt to even the most extreme of life experiences.

CHAPTER 10

GENERAL SUMMARY, DISCUSSION AND CONCLUSIONS

10.1 Summary of rationale and main aims

Recent developments in reconstructive techniques and more sophisticated treatment regimes for HNC have not automatically lead to an increase in survival rate. Therefore, conservation and reconstruction procedures, speech therapy and prostheses have been directed towards lessening the impact of the disease and its treatment in terms of quality of life. A critical review of the literature (see Chapter 2) highlighted that HR-QoL is considered an important patient centred outcome following treatment for HNC. This has been demonstrated by the vast number of studies incorporating assessments of HR-QoL. The review highlighted that the majority of studies have been aimed at comparing the effects of different treatment modalities and tumour characteristics, and have therefore only provided information about the effects of treatment and disease related factors on HR-QoL. This has resulted in valuable information about the effects of disease sites and treatments on HR-QoL, however few studies have attempted to account for other reasons why variation in QoL (both between patients and over time) occurs.

This thesis explored the role of psychological factors in predicting QoL in patients diagnosed and undergoing treatment for HNC using a self-regulatory framework (Leventhal et al., 1980; Leventhal et al., 1992). The primary aim of the thesis was to investigate the relationship between illness and treatment beliefs and both standardised HR-QoL and individualised QoL.

There were seven key objectives for the research:

There were seven key objectives for the research:

- To explore the informational needs of HNC patients and the relationship between satisfaction with information and key outcomes *(Chapters 4, 5: Part 2 & 6).*

- To assess the impact of HNC on QoL using two distinct measures: a) standardised measures of HR-QoL (generic and cancer specific) and b) an individualised (patient centred) measure of QoL *(Chapters 7 &8).*
- To assess the degree of concordance between the two main types of outcome measures *(Chapter 7).*
- To apply Leventhal's Self-regulatory model (SRM) to guide understanding of the processes by which HNC patients understand and react to their illness and to assess how these change over time *(Chapters 7 & 8).*
- To investigate how particular variables specified within the SRM (e.g. illness representations and coping responses) are related to outcomes *(Chapters 7 & 8).*
- To explore whether additional factors such as the extent to which patients are satisfied with information, can partially explain outcomes *(Chapters 6 & 8).*
- To explore whether psychological factors (illness and treatment beliefs) or clinical and treatment related variables are better predictors of adaptation over time *(Chapters 8 & 9).*

10.2 Summary of main results

10.2.1 The role of information in QoL

Literature from other clinical areas (chapter 3) highlighted that pre-treatment expectations were influential on outcomes such as; QoL (Koller et al., 2000), HR-QoL (Staniszewska, 1999; Wan et al., 1997) and functioning (Iversen et al., 1998; Mahomed et al., 2002) in a wide range of illness groups such as cancer, cardiac and arthritis patients. Based on Calman's contention that QoL assesses the 'difference, or the gap, at a particular period of time between the hopes and expectations of the individual and that individual's present experience' (Calman, 1984a; Calman, 1984b), a pilot study was conducted in order to examine the relationship between the fulfilment of expectations, the role of information and subsequent QoL.

The qualitative study produced in-depth data about the types of expectations individuals with HNC had at various stages of their treatment and recovery (chapter 4). Large variations were revealed between patient expectations and the actual experiences that were described. Expectations seemed to be derived in part from the information received. The study also highlighted the individual nature of the information giving process, whereby many patients did not want too much detailed information about their illness and treatment, especially at the early stages between diagnosis and treatment, yet many respondents required a detailed breakdown of all the possible complications and variables associated with the recovery process. These differences in requirements may have been due to differences in personality and/or coping strategies between patients although these relationships could not be determined in the present study. Previous research has indicated that stable individual differences exist between patients' tendencies either to seek or to avoid potentially stressful information about cancer and other threatening medical procedures (Miller, 1992).

Analyses of data from the prospective study demonstrated that satisfaction with information before treatment was predictive of outcomes 6-8 months after treatment (chapter 8). Satisfaction with the amount and content of information was negatively associated with depression scores (Table 8.14) and positively related to MCS scores (Table 8.12), indicating that higher levels of satisfaction prior to treatment were predictive of better QoL and lower levels of depression. Satisfaction with the form and timing of the information was predictive of overall expectations being fulfilled 6-8 months after treatment.

10.2.2 The impact of HNC on QoL

Literature reviews (chapter 2) highlighted the morbidity and depression resulting from treatment for HNC, although these outcomes were shown to improve within one year. In the long-term, despite an initially high level of depression, a gradual improvement in psychological functioning and global QoL follows over the next few years. However, a subgroup of patients

who continue to experience high levels of psychological morbidity years after treatment has frequently been reported and it is important to note that this has not been shown to be related to physical functioning.

To date there has been little attempt to explain variations in QoL and although factors such as stage, site of disease and type of treatment, have some impact on HR-QoL, it is unclear what additional factors account for the large variation evidenced in patient outcomes. Authors in the field are beginning to acknowledge that an individual's QoL is probably determined more by their perceptions of the disease than the disease itself (Sehlen et al, 2002).

Of the psycho-social and behavioural factors identified from a systematic review of the literature (chapter 2, part 2), a number of important relationships were reported. The relationship between personality traits (extraversion/neuroticism, and dispositional optimism) and outcome in HNC was established in several studies (Aarstad et al., 2003; Allison et al., 2000; Yu et al., 2001; Yu et al., 2003). The role of social support was less clear, although satisfaction with physician support was found to account for a significant proportion of variance in outcome (Mathieson et al., 1996). Satisfaction with information was also found to be related to outcome over time (Yu et al., 2001). The relationship between depression and QoL was also unclear with mixed study findings. The literature reviews highlighted the relative lack of research exploring the influence of psycho-social factors on HR-QoL in HNC and demonstrated the need for more robust and theoretically based studies in this area.

10.2.3 The relationship between variables specified within the SRM (e.g. illness representations and coping responses) and outcomes

Research on lay experiences of illness has found that coming to terms with an illness event involves patients interpreting why the event has happened, how it can be further prevented and how its effects can be overcome (Bury, 1991). This process may be better understood by

applying a framework such as Leventhal's Self-Regulatory Model (SRM) (Leventhal et al., 1980). The Self-Regulation Model proposes that in response to a health threat, such as the diagnosis of cancer, individuals develop their own beliefs and emotional responses about their illness and treatment, which then influence the coping procedures they adopt. These beliefs, emotional responses and coping strategies then influence the outcome, which, in this study, were perceptions of QoL. As this is a constant process of reappraisal, patient beliefs and coping strategies may be expected to change over time.

10.2.3.1 Individualised QoL versus HR-QoL

Although standardised (or traditional) HR-QoL measures are often used with HNC patients within a clinical setting, it has been suggested that they fail to capture the individual's sense of 'quality of life'. This is because they focus on the individual's perception of QoL but only related to pre-selected domains. In contrast, patient generated outcome (individualised QoL) attempts to capture aspects of QoL that are most important to the individual at that particular time point. Given the interest in the use of individualised measures in clinical trials (Campbell et al., 2000; Patel et al., 2003) and with cancer patients in general (Camilleri-Brennan et al., 2002; Lindblad et al., 2002; Waldron et al., 1999), an individualised measure of outcome was applied in comparison to HR-QoL in this thesis (chapters 7 and 8). Moreover, suggestions made by Leventhal and Colman (1997), indicated that individualised measures may provide better outcomes for predictive studies based on SRM components than HR-QoL, *as 'the judgement of quality is a product of both the individual's assessment of his or her personal experience within a variety of domains and the integration of these observations into an overall judgement...'* (Leventhal and Colman, 1997).

It was hypothesised that there would be no relationship between pre-treatment standardised assessments of HR-QoL and the individualised measure of QoL due to their conceptual differences. The results of our study (chapter 7) suggested that there was partial overlap

between these measures pre-treatment and that the main overlap appeared to exist between individualised QoL and the cognitive, emotional and mental health HR-QoL domains of the standardised measures (Table 7.5). These results suggest that the individualised measure was tapping into the emotional and cognitive impact of being diagnosed with HNC.

10.2.3.2 The relationship between illness perceptions and QoL

In the present study, a significant amount of variation in pre-treatment HR-QoL could be explained by patient's perceptions of their illness (chapter 7). In particular, patients' Illness Identity (the amount of symptoms attributed to their HNC) and beliefs about the likely Timeline (perceptions about the length of time the illness would last) explained a significant amount of variance in HR-QoL and Global QoL (Tables 7.7 & 7.9). However, surprisingly, it was found that components of the SRM could not explain any of the variance in individualised QoL. Individualised QoL was only associated with the emotional response to the illness in the form of anxiety levels (Table 7.10).

The literature demonstrated that patient beliefs and outcomes change over time (chapters 2 and 3). Therefore, a longitudinal study was essential in order to determine whether the relationships between key components of the SRM and outcomes found at baseline were similar to those shown over time.

Chapter 8 highlighted the dynamic nature of illness and treatment representations, with significant changes over time shown in key patient beliefs. Perceptions of the necessity of treatment significantly increased over time and correspondingly, patients' understanding of their illness significantly increased (Figure 8.2). Interestingly, patients' beliefs about the personal controllability of their illness significantly decreased over time from baseline perceptions. In addition to these changes, patients' perceptions of the consequences of their illness were also less negative. These changes indicate that as patient's beliefs change over time, they may also be

modifiable and are independent to illness identity (i.e. levels of symptoms they are currently experiencing). Not much is known about how beliefs change over time and what brings about these changes. However, the significant changes highlighted in this chapter suggested that beliefs may be associated with positive adaptive processes as other outcomes also generally improved over time (Figure 8.1).

Pre-treatment illness and treatment perceptions were not found to be significant predictors of any of the QoL outcomes assessed 6-8 months after the end of treatment (PCS and MCS scores, Global QoL/health status and individualised QoL). This was a surprising finding and is discussed in more detail in section 10.3.1. Perceptions of the extent to which expectations had been fulfilled were predicted by beliefs about the consequences of the illness and the emotional response to the illness (Tables 8.16 & 8.18).

10.2.3.3 The relationship between coping strategies and QoL

The literature supports the notion that patient beliefs may be more predictive of outcomes than coping mechanisms (chapter 3); however, the SRM and the present data do not maintain this view.

Pre-treatment coping strategies were related to pre-treatment QoL in the present study (chapter 7). In particular, the use of more adaptive strategies, such as positive reframing, were associated with better QoL, and maladaptive strategies such as substance use and self-blame were associated with worse QoL. For example, higher levels of self-blame were associated with lower levels of global QoL (Table 7.9) and higher levels of reported substance use were associated with poorer mental QoL (MCS score) (Table 7.8). The direction of causation is not known, but it is feasible that less adaptive coping leads to poorer QoL. It is equally as plausible, however, that perceptions of poor QoL lead to difficulties coping effectively.

It is also worth reiterating that more maladaptive coping styles were also positively associated with more negative illness and treatment perceptions (Table 7.11). For example, higher levels of denial, substance use and venting were associated with perceptions of more negative consequences, greater concerns regarding treatment, and a greater emotional response to the illness. High levels of denial were also associated with lower levels of understanding (coherence) regarding their illness.

Coping strategy was found to be significantly predictive of only one longitudinal QoL outcome measure; Global health status/QoL (chapter 8). Levels of acceptance coping were negatively related to Global health status/QoL indicating that lower levels of acceptance were reported by individuals experiencing high levels of QoL (Table 8.10). This may appear to be contrary to expectations but, it may be that acceptance is related to severity of symptoms and impairment resulting from the cancer, or indeed states of denial. Patients reporting high QoL may be un-accepting of their cancer due to denial or because they have very little by way of signs and symptoms to remind them of their cancer diagnosis.

10.2.4 The relationship between optimism and QoL

In contrast to previous research (Aarstad et al., 2003; Allison et al., 2000), dispositional optimism was not found to be an important explanatory variable of QoL in the prospective study. At baseline, optimism was not associated with any of the outcome measures (chapter 7), and was only predictive of Mental Component Summary (MCS) scores 6-8 months after treatment when higher levels of optimism were associated with higher MCS scores (chapter 8).

In contrast, the cross-sectional study assessing the subjective well-being of HNC patients demonstrated that the most important determinant of cognitive adaptation throughout the analyses was level of optimism (chapter 9). The disparity between the results from the prospective study and the cross-sectional study may be explained by several factors. Firstly,

different outcome measures were used in the studies and additional explanatory factors such as illness and treatment perceptions were not present in the cross-sectional study. Personality may exert an indirect influence through the types of beliefs held, which disappears when illness perceptions are included in the analysis. Alternatively, the inconsistent pattern of associations found between optimism and outcomes is consistent with ideas of Segerstrom and colleagues who maintain that a more flexible model of optimism should be considered, whereby the context of the stressor is taken into account along with the degree of 'disappointment' the individual experiences as a result (Segerstrom, 2005).

10.2.5 Depression

Levels of depression in the literature have been shown to vary considerably in HNC (see Chapter 2). However, levels in the present sample were found to be similar to pre-treatment levels reported in both cross-sectional and prospective designed studies (D'Antonio et al., 1998; de Graeff et al., 2000b). It is possible, however, as higher levels have been reported in the literature (Birkhaug et al., 2002; Duffy et al., 2002) that the present sample is not representative of all patients with HNC and that patients with higher levels of depression did not take part.

As expected, depression explained some of the variance in HR-QoL at baseline (Tables 7.7 & 7.8), which is consistent with previous research (de Graeff et al., 2000b; Hammerlid et al., 2001b). Surprisingly, baseline depression and longitudinal outcome were not found to be related as other prospective studies have suggested (D'Antonio et al., 1998; de Graeff et al., 2000b). This reveals that when other psychological variables are taken into account, the relationship between depressive symptoms and QoL diminishes, and that QoL is not just a proxy indicator of depression. It was also interesting to note that variance in patient generated QoL was not explained by depressive symptoms at either time point.

Regarding depression as an outcome variable, half of the variance in baseline scores was explained by illness identity, anxiety and feelings of self-blame (Table 7.13). Associations were positive, indicating that higher scores on these three measures were related to higher depression. Longitudinal levels of depression were predicted by baseline beliefs regarding the expected duration of the illness (timeline beliefs), self-blame, levels of acceptance coping, and satisfaction with information (just after treatment).

10.2.6 Were treatment and clinical related factors better predictors of adaptation over time than patient related factors?

The results presented in chapter 8 indicated that only tumour stage was related to outcomes (Global health status/QoL, individualised QoL, and expectations regarding the extent of recovery). The relationship was inverse indicating larger tumours were associated with worse outcomes. None of the other clinical and treatment related factors proved significant. Similarly, findings from chapter 9 indicated that only treatment modality was related to cognitive adaptation (satisfaction with life).

Having had 'surgery only' was found to be protective of satisfaction with life which may have been due to less time taken to heal, as opposed to the long term effects of radiotherapy (Table 9.8). Alternatively, 'surgery only' may have been acting as a surrogate marker for tumour size or tumour severity as larger tumours are more likely to be treated with multiple modes of treatment. Analysis with stage data was not found to be significant, however. From these results it appears that patient related factors such as patient perceptions, coping strategies and levels of satisfaction with information were better explanatory factors of outcome than any clinical or treatment related factors.

10.3 Theoretical implications

A key aim of this thesis was to examine the utility of the SRM in predicting outcomes in HNC. Furthermore, if this model proved constructive in the understanding of adaptive processes in this patient group, factors found to be predictive of outcomes and potentially modifiable may be used to inform future intervention studies to enhance patient outcomes after treatment.

10.3.1 The application of the SRM to guide understanding of the processes by which HNC patients understand and react to their illness

Chapter 3 highlighted the wealth of evidence linking components of the SRM to outcomes such as QoL or depression in various illness groups (Moss-Morris et al., 2003; Rutter et al., 2002; Vaughan et al., 2003). However, a criticism of these studies was that the majority were based on cross-sectional data and thus the direction of causation cannot be established. Literature searches highlighted that there had been no previously published work examining this relationship in HNC patients.

The SRM framework was useful in guiding the original selection of factors to be included in the current research. The IPQ and BMQ instruments had not frequently been applied to the area of cancer and thus not much was known about their suitability for use with HNC patients.

Components of the SRM such as illness perceptions and coping strategies were found to be better explanatory factors of dependent variables such as HR-QoL and depression at baseline than longitudinally. In particular, beliefs relating to illness identity, timeline, and emotional representations were significantly related to outcome, in addition to coping strategies such as substance use, self-blame, self-distraction, venting and use of instrumental support. Particular outcomes were more successfully explained by components of the SRM than others. For example, approximately half of the variance in pre-treatment Global health status/QoL was explained by coping strategies and illness beliefs alone. Likewise, a large proportion of anxiety and depression at baseline were explained by SRM components.

However, baseline illness and treatment perceptions and coping strategies were not found to be predictive of the majority of outcomes at longitudinal follow-up. Depression was an exception to this rule, with 67% of the variance predicted by psychological factors of; timeline beliefs, self-blame, acceptance coping and satisfaction with information. This finding is, however, consistent with the SRM which maintains that a person's cognitions and behaviour influence outcomes *at that time* and cognitions and behaviour at one point of time would not necessarily be expected to influence outcomes at another time point in the future.

The results have indicated that the SRM was valuable in providing information about the underlying psychological determinants of a variety of outcomes at baseline. It was also useful for examining the extent to which patient's beliefs and coping strategies at the time of diagnosis affected levels of depression over time. The SRM proved limited for predicting other longitudinal outcomes, however, the SRM does not actually specify direct relationships between illness beliefs and outcomes or relationships over time (as mentioned previously). The model stipulates that illness beliefs guide coping, and the model proved successful in establishing a link between these two components.

In terms of the utility of the SRM for the design of interventions, findings from the current research indicate that any positive effects of intervention would be limited if solely based on illness representations and coping strategies. However, these psychological factors were more successful in explaining outcomes than any demographic or clinical factors, which provides promising data for intervening in the case of vulnerable patients.

10.3.2 Alternative theories on which to base research into adaptation in HNC patients

An alternative theory on which to base studies examining adaptation in people who are confronted with a serious health threat is Taylor's theory of cognitive adaptation (Taylor, 1983). As applied in chapter 9, Taylor's theory of cognitive adaptation suggests that people may

use a number of cognitive strategies to counteract the negative impact of distress on well-being. Taylor argues that when an individual experiences a personally threatening event, the readjustment process focuses around three themes: a search for meaning in the experience, an attempt to regain mastery over the particular event and life in general, and an effort to restore one's self-esteem (Taylor, 1983). Research has demonstrated that patients who were successful across these three themes, were emotionally better adjusted than those who were unable to form and maintain this set of illusions or perceptions (Taylor et al., 1984). The majority of research based on Taylor's theory of cognitive adaptation has focused on the assessment of optimism, control and self-esteem to represent the theory's three components. It may be fruitful to examine adaptation from the perspective of this theory and use the three themes outline above as a basis for intervention in individuals who do not show adaptation over time. Further work may determine whether this theory is more appropriate to the study of HNC patients than the SRM.

10.4 General critique/limitations of the research

The specific limitations of each study have been addressed in some detail in each chapter, however, a discussion of a number of more general limitations and criticisms can be found in this section.

10.4.1 Theoretical issues

The majority of the research in this thesis was based on the SRM, however, it was not possible to fully test this model due to its complexity. In particular, it proved difficult to capture the dynamics of when and how changes to outcome occurred and what factors in particular caused the change. The problem with using formulaic measurement times to assess process factors and outcome i.e. at 1 month and 6 months etc, is that changes can not be captured exactly when they occur, and the variability between people in terms of when changes occur can not be observed. A key component of the SRM is the appraisal process, and similar to the majority

of studies applying the SRM, this part of the model was not tested. The appraisal stage of the model is critical in understanding outcomes as it accounts for the two-way process between the beliefs people have and the coping strategy they employ. This then has repercussions for outcome. The appraisal mechanism is rarely assessed as it is difficult to capture when it occurs and how it manifests. Attempts could be made to assess this process through interviewing, although the full extent of this process may be obscured in patients who are less aware of it occurring. Until we fully understand the mechanism of appraisal and its relationship between coping and beliefs, it is impossible to establish how important this process is in influencing outcome.

10.4.2 Measurement and analytical issues

The QoL questionnaires used in the thesis may have substantial overlap with the attributes of illness representations assessed by the IPQ (e.g. illness identity overlaps with symptom experience, emotional representations may tap into emotional functioning, etc). This may partially explain associations between illness representations and outcomes. However, this would not explain why timeline beliefs were key explanatory factors, and existing outcome measures typically neglect the effect of time-line and control on QoL and do not address beliefs relating to treatment.

Many of the measurement tools used in this research were not validated, for example the SCIP and the three items to assess expectations (pages 183-185). The decision to use non-validated measures was taken as no other suitable validated measures existed. Preliminary work supported the usefulness and psychometric properties of these measures, however, further research is needed with additional patient samples in order to comment on the absolute reliability and validity of these particular measures.

A problem with QoL data in general, is that there is an inherent bias towards those that are better off and indeed those that have survived. Follow-up data tends to be skewed towards those with earlier stage tumours and therefore less physical consequences of treatment. A comparison of those that were originally recruited into the study and those that remained at follow-up, demonstrated a significant difference in tumour stage, with those remaining in the study being diagnosed with earlier stage tumours at the outset. Relatively large attrition rates for a number of reasons, limits the generalisability of the results. A recent paper attempted to clarify whether there was a more appropriate way to statistically analyse longitudinal QoL data due to issues of dropout (Curran, Molenberghs, Aaronson, Fossa, & Sylvester, 2002). The authors suggest that modelling approaches such as selection models and pattern-mixture models may be useful when considering the effects of drop-out on the data. However, these methods may be more pertinent to examining treatment effects across a large group rather than individual patterns.

Alternatively, cluster analysis may be a more appropriate method of analysis for small data sets such as those generated from HNC samples. Cluster analysis is a tool of discovery which is useful for revealing associations in data which may not be previously evident. For example, it may be useful to know whether there is a pattern between illness representations or indeed relationships between illness representations and outcomes. Cluster analysis could also be used to create individual patient profiles of factors of interest such as beliefs and coping strategies which could then be used as a basis for one-to-one interventions (Clatworthy, Buick, Hankins, Weinman, & Horne, 2005; Hobro, Weinman, & Hankins, 2004). Indeed, a limitation of much of the work using the SRM, the present work included, is the assessment and reporting of beliefs on an individual basis. The SRM was intended to examine obvious clusters of beliefs in order to provide a schematic model, and therefore not necessarily providing an assessment of individual illness representations.

Regarding the power of the study, many of the models may not have been adequately powered due to low sample sizes. This was due to the fact that HNC is a relatively rare disease, made worse by problems with recruitment. A larger multi-centred site is required to harness sufficient cases in the time period and understand any regional variations. In addition, to this, large numbers of statistical tests applied to the data meant an increased possibility of a resultant Type I error. The significance level of the tests could have been lowered; however, this inevitably would have increased the Type II error rate.

10.4.3 Length of follow-up

The follow-up time of the longitudinal study was limited to six to eight months post treatment due to time and funding. Time taken to complete treatment varied considerably between patients and some patients had not finished treatment up to four to five months after diagnosis. This meant that some of the patients had a shorter follow-up period than others. Important changes may occur between six and eight months into recovery, especially in the case of late toxicities of radiotherapy treatment, and using an arbitrary cut-off such as this may have meant that factors and beliefs that might impact outcomes over a longer term were obscured.

It would be of further interest to investigate whether baseline factors found to be predictive of outcomes at six to eight months after treatment, were predictive of longer-term outcomes or whether the relationships between beliefs and outcomes change over time as suggested by the results of chapters 7 and 8. Further research could extend the study for longer than was feasible in the present study. This would have further implications for the utility of intervention at different time-points.

It is also acknowledged that other factors may have had an influence on outcomes for several reasons. Firstly, from the literature reviews presented here and wider reading, additional psychological variables, such as social support, may affect QoL and depression. Secondly, a substantial amount of variance was unaccounted for in the models presented in this thesis, thereby suggesting that other factors are exerting an influence on outcome. Social support has shown to buffer the negative consequences of illness (Kornblith et al., 2001) under the right circumstances, and it is reasonable to assume that access to appropriate social support may impact on QoL, either directly or via perceptions or coping strategies. Further research could investigate this aspect in more detail.

10.5. Clinical implications and recommendations based on research findings

10.5.1 Early recognition of vulnerable individuals

The findings from the studies in this thesis indicate that there may be scope to provide both general and individualised interventions. Results have suggested that individuals who may have problems adapting over time could be identified by assessing dispositional factors such as low levels of optimism. Head and neck nurses trained to identify patients at risk early on could provide additional support or rehabilitation on an individual basis.

Head and neck cancer services require additional specialist HN nurses trained to provide advice, tailored information provision and appropriate counselling to patients in need. Better access to specialist counselling or psychological support services within the hospital (and not via the GP) would be recommended in cases where the patient's level of distress is not diminishing and depression levels not improving over time.

10.5.2 Tailoring information to meet an individual's need

Chapters 4 and 6 highlighted that HNC patients have differing needs for information and vary in their levels of satisfaction. Written materials provided for HNC patients typically consist of

generic information, often in the form of pamphlets or booklets and were designed for generic use amongst all patients with HNC. Although these materials are a cost-effective method for providing valuable generic information, it could be argued that their one-size fits all approach is not sensitive to the variation that exists between people in their desire for and understanding of information (Kreuter et al., 1999). Satisfaction with information has been shown to be associated with particular patient beliefs (although the direction of causation is unclear) and has been shown to influence whether patient's expectations have been met after treatment. With this in mind and, as recommended by other authors (Newell et al., 2004; Semple et al., 2002), it would seem judicious to assess HNC patients needs for information on an individual basis.

Technological advances mean that highly customised materials could feasibly be designed on an individual basis. Materials could be tailored to multiple aspects of the individual, providing information that fits their lives better than generic materials currently used (Holt et al., 2000). Although this is a new area for providing health education messages, it could feasibly be applied for understanding patient's individual requirements for information instead of the professional providing information they consider valuable. Further research could investigate the feasibility and design of tailored information and messages for HNC patients and cancer patients in general.

An association between satisfaction with information and outcomes such as global QoL and depression was found. Consequently, satisfaction with information could be an important target for intervention in order to improve short-term and long-term patient well-being. Targeting unmet informational needs could prove a cost-effective and relatively simple intervention.

An additional positive aspect of enhancing patient satisfaction with information, by providing a good match between the provision of information and patients' requirements, is the promotion

of partnership between the patient and the health care professional. The need for good communication between health professionals and patients is emphasised in current NHS policy (NHS Centre for Reviews and Dissemination, 2000) and also serves to aid the decision making process by empowering the patient (Grahn, 1996).

10.5.3 Access and advertisement of specialist support groups

Another key area to emerge from this thesis was the scope for improving the provision of information about support groups. Over half of the current sample had not received any information about support groups prior to their treatment and a third reported the same one month after treatment. A report by The King's Fund (1997) found that many HNC patients did not know of the existence of support groups and that some professionals did not advertise support groups as patients did not ask for them (Edwards, 1997). It appears that not much has changed since this report. Local support groups known specifically for HNC patients and partners existed at many of the recruiting sites, and information about these could be supplied regardless of whether patients explicitly ask or appear to have difficulties coping. Patients' perceptions of these groups could also be challenged through better advertising of the activities available at the groups and through actively inviting patients and supporters as part of routine practice.

10.5.4 Teaching patients coping strategies

Our findings suggested that coping strategies may be better predictors of outcome than patient beliefs. Better levels of QoL were associated with 'adaptive' coping strategies such as positive reframing. Worse outcomes were associated with higher levels of substance use and self-blame. Over the longer term, higher levels of acceptance coping were predictive of better Global QoL. Previous attempts have been made to teach HNC patients coping strategies using psycho-educational interventions in order to improve QoL (Allison et al., 2004). Their intervention

focused on enhancing a sense of personal control and learning emotional and instrumental coping responses. Although modest benefits were reported, the intervention was not tailored to the individual and did not necessarily address the patient's requirements or deficits. In terms of providing a clinic based intervention, patients' individual coping styles could easily be assessed at different time points and addressed in a more personal and meaningful way. Reducing maladaptive coping, such as high alcohol and substance use could be addressed through counselling alongside teaching alternative (and less harmful) ways of coping.

10.5.5 The utility of assessing individualised QoL as part of clinical practice

With regard to generating specific information about patients, individual QoL assessment has value. However, for large scale clinical studies examining changes in QoL after treatment etc, it would not be appropriate to use highly individualised QoL statements. Patient generated measures such as the PGI can be difficult to interpret and use in a meaningful way. Due to this, patient generated outcome measures may be appealing for use in clinical practice, however, they are probably best used as an adjunct to traditional HR-QoL measures.

10.6 Implications for further research

Several key areas emerged as important areas for further study. Firstly, the SCIP gave promising results when used in the present studies, however, further validation of its psychometric properties is needed as the instrument has essentially only undergone preliminary testing. If the instrument was found to be valid and acceptable in further research, it may prove a useful tool both clinically and to further understand relations with outcomes in research settings.

Satisfaction with information was predictive of beliefs regarding the necessity of treatment and how important the treatment was in controlling their disease. One explanation for this could be that patients are getting the information too late and the importance of the treatment has not

been fully recognised. Although all the patients in this sample underwent some form of treatment, this finding is noteworthy and it would be valuable to further investigate whether beliefs about treatment and control after undergoing primary treatment are predictive of adherence to further treatment, or are influential in the decision making process prior to primary treatment.

The preliminary work presented in this thesis on patient expectations provided some interesting findings and the present research could be extended to examine the relationship between informational needs, expectations and patient outcomes in more detail. The literature suggests that pre-treatment expectations can influence post-treatment outcomes (Iversen et al., 1998) and it would be interesting to further validate the items used to tap into expectations in this thesis and explore these and other relationships more robustly.

The next stage in this work would be to design and implement interventions with the aim of improving post-treatment QoL and psychological adaptation. Tailored interventions could therefore address particular beliefs such as treatment concerns and the time scale of the illness, and focus on fostering more adaptive coping strategies such as acceptance and the use of emotional and instrumental support, whilst avoiding maladaptive coping strategies, such as self-blame and substance use. One avenue could be through the use of cognitive-behavioural approaches aimed at altering the negative beliefs about the treatment and course of the illness whilst encouraging a sense of control over the illness. Other methods of coping such as seeking social support and accepting the situation could be offered as alternatives to avoidance coping such as self-blame and using substances such as drugs and alcohol. It may be feasible to implement more simple interventions through support groups with the aid of specialist nurse-counsellors.

Assessing subjective well-being (cognitive and emotional adaptation) appears to be promising for use in clinical practice and may provide additional information to standard HR-QoL measures. The patient samples used in chapter 9 demonstrated that positive cognitions may be reported in patients irrespective of severity of illness. To understand which individuals are able to cognitively and emotionally adapt after a threatening event such as cancer, further research should examine individual differences in positive cognitions. Intervening in those patients who do not show signs of adapting could be valuable in enhancing their satisfaction with life and reducing psychological distress. Possible interventions could include one to one counselling or cognitive behavioural therapy to decrease levels of depression.

Another area of research could be to build on the cross-sectional study presented in chapter 9 by examining the process variables underlying adaptation. This could be achieved using a longitudinal study design guided by either Taylor's theory of cognitive adaptation (Taylor, 1983) or Leventhal's SRM (Leventhal et al., 1984). This would provide data on the dynamic process of adaptation and would provide more information on the relationship between cognitive and emotional adaptation and whether change occurs in parallel.

10.7 Conclusions

The cross-sectional and prospective studies contained in this thesis have increased our understanding of the predictors of QoL in HNC patients.

Important relationships were found between components of the SRM such as illness beliefs and coping, and outcomes. Psychological factors such as these were found to be better predictors of outcome and adaptation than either clinical/treatment related factors or socio-demographic factors.

If the findings of this thesis can be replicated in other samples of HNC patients, this has important implications for the design of evidence based interventions in order to facilitate

adaptive coping strategies and improve patient outcomes (both cognitive and emotional). Eliciting and addressing negative perceptions of the consequences of the disease and treatment, whilst maintaining strong perceptions of the necessity of treatment and helping patients cope in more adaptive ways could be feasible targets.

More generic interventions could also be devised such as the early recognition of vulnerable people due to dispositional and situational factors. These individuals could be provided access to specialist rehabilitation services, or cognitive behavioural counselling for those that need help with adapting after treatment. Other important targets for intervention could include the provision of individualised information and the promotion of awareness of support groups.

APPENDICES

APPENDIX I: BREAKDOWN OF SYSTEMATIC LITERATURE REVIEW SEARCH STRATEGY AND RESULTS

Search Strategy and results

#	Search History	Database and preliminary results						
		MEDLINE	PsycINFO*	EMBASE	CANCERLIT	CINAHL	SSCI & SCI-expanded‡	ISI proceedings‡
1	exp "Head and Neck Neoplasms"/	143358	-	58924	97627	2976	-	-
2	Quality of Life/	38788	6264	38815	8766	7265	-	-
3	1 and 2	690	-	553	575	87	-	-
4	limit 3 to yr=1980-2003	674	-	553	575	87	-	-
5	limit 4 to english language	536	-	468	448	87	-	-
6	cancer$.tw.	418387	10877	329832	418835	23733	>100000	44686
7	carcino$.tw.	309707	375	246975	330772	1869	>100000	25831
8	neoplas$.tw.	110239	367	81439	109550	782	94808	7413
9	tumo?r$.tw.	565823	1685	450302	585282	3262	>100000	37630
10	"head and neck".tw.	24901	220	21029	21914	1180	25009	3312
11	oral.tw.	213950	12400	163071	41359	8043	>100000	12029
12	mouth$.tw.	28666	2131	16434	4956	1342	19504	2067
13	hypopharyn$.tw.	3034	1	2419	2543	61	1911	327
14	tongue.tw.	14868	1648	9554	5804	478	10867	952
15	laryn$.tw.	35124	506	24485	15420	1359	21961	2814
16	oropharyn$.tw.	6688	72	5584	3498	238	5109	581
17	pharyn$.tw.	17118	141	12759	5215	476	11557	1159
18	tonsil$.tw.	12399	71	8553	3558	303	6827	686
19	esophag$.tw.	54297	298	37311	23430	842	49969	4430
20	oesophag$.tw.	16354	29	13377	4374	189	9149	654
21	salivary$.tw.	26936	936	16237	7919	416	21370	1149
22	tracheal$.tw.	21937	20	17448	3128	438	18291	1236
23	submandibular$.tw.	7004	19	4570	1642	79	4894	255
24	otorhinolaryn$.tw.	3423	19	1646	621	62	885	124
25	nasopharyn$.tw.	11759	44	8916	7613	244	8292	834
26	parotid gland.tw.	5429	20	3679	2894	69	3831	223
27	6 or 7 or 8 or 9	1013567	12565	780597	971319	27317	>100000	76471

28	10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26	431878	17592	313649	115214	13717	>100000	26924
29	quality of life.tw.	36287	9311	32333	11904	7530	38056	5308
30	qol.tw.	3084	1154	2823	1260	626	2658	359
31	health state$.tw.	1343	268	938	176	203	959	125
32	29 or 30 or 31	37706	9520	33258	12228	7708	38682	5389
33	27 and 28 and 32	1473	34	1248	1484	149	305	226
34	limit 33 to (english language and yr=1980-2003)	1102	30	998	1120	148	294	54 (from 1990)
35	5 or 34	1320	30	1224	1297	186	294	54
36	(questionnaire$ or interview$).tw.	166697	152005	126243	17016	41268	>100000	-
37	**35 and 36**	**260**	**12**	**248**	**245**	**53**	**68**	**54**
N= articles selected by preliminary examination of titles and abstracts.[a]		**137**	**7**	**124**	**102**	**32**	**63**	**12**
N= articles fulfilling criteria for inclusion, selected using data extraction sheet.		**16**						

* No subject headings to search on database.
‡ truncated term is * not $
[a] These contain duplicates across the databases.

APPENDIX II: SYSTEMATIC LITERATURE REVIEW DATA EXTRACTION SHEETS

APPENDIX II: Preliminary data extraction sheet

Ref no:
Reviewer:

A DETAILS OF PUBLICATION
Author.....
Title.....
Reference.....
Country study sample derived
from.....

B RESEARCH Q/HYPOTHESES
a) Aim
b) Outcome

C STUDY DESIGN
a) Recruitment procedures reported?
b) Cross-sectional,
Prospective/ longitudinal
c) Time since diagnosis/treatment
d) Control patients / comparison group reported?

D i. PARTICIPANTS
no. of patients
patient characteristics in study
i.e. cancer type (SCC etc)
site of cancer,
stage of cancer
treatment
or whether mixed sample reported
recurrent cancer?
complications reported?
neck dissections reported?
age, sex, class, ethnicity, geographic location, other info
Is sample representative of study population?
i.e. recruitment rate
response rate
inclusion/exclusion criteria?

ii. CONTROL PATIENTS / COMPARISON GROUP (if applicable)
no. of patients
patient characteristics in study
i.e. cancer / no cancer
site of cancer
stage of cancer
treatment
or whether mixed sample reported
recurrent cancer?
complications /neck dissections?

age, sex, class, ethnicity, geographic location, other info

Is sample representative of intended population?
i.e. recruitment rate
response rate
inclusion/exclusion criteria

E OUTCOME MEASURES
Who carried out measurement?
What was the measurement tool?
Was the reliability and validity reported:
- in literature?
- for particular study sample?

What was measured at baseline?
Time interval between measurements?
Other sources of information used

F ANALYSIS
Statistical techniques used?
What factors were adjusted for?
What variables were included in analysis?
Power calculation?

G RESULTS
Group differences
Particular HR-QoL subscales found to be impaired?

H AUTHOR COMMENTS
Conclusions from study
Inferences from study

I OTHER CONSIDERATIONS/ REVIEWER COMMENTS
Strengths/weaknesses of study

APPENDIX III: SYSTEMATIC LITERATURE REVIEW CRITICAL APPRAISAL FORM

APPENDIX III: Critical appraisal form

Factor	Weighting	
Study aims/ research Q	Good (2) Aims clear, research Q or hypotheses stated. Adequate (1) Aims stated, no specific research Q or hypotheses. Poor (0) Aims not clear or not stated.	
Study design	Good (2) Prospective or case/ control Adequate (1) Cross-sectional Poor (0) Not clear	
Sample characteristics:	Good (2) Large, representative, well described Adequate (1) Limited info on sample Poor (0) Unable to determine characteristics and representativeness of sample or poor representativeness.	
Analysis	Good (2) Appropriate multivariate analyses, controlling for confounding factors Adequate (1) appropriate but limited/simplistic analyses. Poor (0) analyses inappropriate/ inadequate, likely to give misleading results.	
Statistical power	Good (2) power calculation included or appropriately powered study. Adequate (1) adequately powered going by sample size/analyses Poor (0) v. underpowered going by sample size/ analyses	
Validity of conclusions	Good (2) Accurate and derived from good statistical analyses/design. Adequate (1) Generally supported by results. Poor (0) bear no resemblance to results presented	
Overall score (0 - 12)		

APPENDIX IV: INTERVIEW SCHEDULES

APPENDIX IV

Semi-structured interview schedule

Patient's retrospective accounts of experiences of head and neck cancer: expectations and informational needs

I would like to ask you about the experiences and thoughts you've had in the time since you were first diagnosed. I want to get a better understanding of the sorts of expectations and perceptions people have not only about their illness and subsequent treatment but also regarding the impact to their life in general.

Reassure of confidentiality and anonymity and gain informed consent to use tape recorder.

Opening Q

1. I'd like to start by asking you to tell me a little bit about when you were first diagnosed and the kind of treatment you've had since.

A Expectations:

Now, I'd like you to think about whether you had any expectations regarding your treatment and recovery.

1. Can you tell me whether you had any expectations regarding your treatment? (Prompt: Treatment outcome, what it would achieve? If no particular expectations, why do you think you didn't have any?)

2. Can you tell me whether you had any expectations regarding the recovery process? (Prompt: regarding how you would feel, look, function - immediately after and at X time point after recovery.)

3. [If applicable] This is a difficult question, but, could you tell me whether your expectations have been met? (Prompt: In what sorts of ways / why not?)

4. Looking back, do you think now that you had realistic expectations? (Prompt: In what ways were they realistic/ not realistic?)

5. Did you have any worries or concerns over any aspect of the treatment or recovery? (Prompt: What would happen, procedures, outcome, waking up in hospital, how you'd feel or look, how long the recovery process would take, impact on life, coping etc)

6. Prior to treatment, did you have any expectations regarding what you thought your health would be like now? (Prompt: Better /worse / the same compared to how you feel now?)

7. Prior to treatment, did you have any expectations regarding what you thought your quality of life would be like now? (Prompt: Better /worse / the same compared to how you feel it is now?)

8. Do you think there have been any changes to your life due to the cancer and treatment? (Prompt: e.g. the consequences of treatment, life priorities, feelings, day to day activities/ work/ functioning.... In what way have things changed, why have they occurred, how do you feel about this?)

B Informational needs /role in preparation:

I'd now like to ask you some questions regarding the information you received about your illness and treatment and how satisfied you were with it.

1. Thinking back, were you satisfied with the amount and type of information you were given about your illness and the types of treatment suitable for you? (Prompt: amount, type of info. when given, by whom, info about illness, info about treatment, in what ways satisfied/ not satisfied, what aspects were you most happy/least happy with.)

2. [If not covered] What sorts of information were you given? (Prompt: verbal, reading materials, mixture of both, did you read it all, how well did you understand/ remember what was said/ read.)

3. Were you told in advance about all the procedures you underwent?
(Prompt: anything that happened that was unexpected – in hospital or afterwards.)

4. Were you given information or told about any impact the treatment may have on how you would physically feel? (Prompt: pain, functioning, aesthetically, energy etc)

5. Were you given information or told about any impact the treatment may have on your lifestyle or quality of life? (Prompt: ability to work, housework, daily activities, family functioning, social life etc)

6. Is there anything you wish that you had been told?

7. Were there any side-effects or aspects of the treatment that you wish you'd been warned of?

8. How do you think the information you received helped you to prepare for what happened?

9. Do you think there would be any way of improving how well prepared you felt?

10. Thinking back to when you were first diagnosed and then undergoing treatment, was there anything that you remember feeling uncertain about? (Prompt: Any aspects of treatment or recovery you weren't sure about and why. Any aspects of your life as a whole – financial, family, job?)

APPENDIX IVb: SUMMARY OF QUESTIONNAIRES USED IN THE RESEARCH AND REPORTED IN DIFFERENT CHAPTERS OF THE THESIS

PAGE NUMBERING AS ORIGINAL

APPENDIX IV (b)

Summary of questionnaires used in the research and reported in different chapters of the thesis

	CHAPTER				
	5	6	7	8	9
	Part II				
Page number	190	216	254	279	320
Time points	Baseline, 1mth	Baseline, 1mth, 8mth	Baseline	Baseline, 1mth, 8mth	Cross-sectional, longitudinal
Outcome measures					
EORTC QLQ C30	X	-	X	X	-
SF12v2	-	-	X	X	-
PGI	-	-	X	X	-
SWLS	-	-	-	-	X
HADS	-	-	X	X	X
Expectations	-	X	-	-	-
Predictors/explanatory factors					
IPQ-R	X	X	X	X	-
BIPQ	X	-	-	-	-
BMQ - Specific	X	X	X	X	-
HADS	X	X	X	X	X
LOT-R	X	X	X	X	X
Brief COPE	-	X	X	X	-
SCIP	X	X	-	X	-
Expectations	-	-	-	X	-
SF12v2	-	-	-	-	X

APPENDIX V: PATIENT INFORMATION LETTER FOR PROSPECTIVE STUDY

Guy's, King's and St Thomas' School of Medicine
Psychology Unit

5th Floor Thomas Guy House
Guy's Campus
London SE1 9RT
Direct line tel: +44 (0) 20 7955 5000 ext
Departmental tel: +44 (0) 20 7955 4965
Departmental fax: +44 (0) 20 7955 2727

KING'S College LONDON

University of London

APPENDIX V

PATIENT INFORMATION SHEET Version 2

Study of quality of life in patients with head and neck cancer

We are a research team at Guy's Hospital, London who are carrying out a study examining the quality of life in patients with head and neck cancer. We would like to invite you to help us with our research. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

What is the purpose of the study?

We would like to find out what factors affect the quality of life of people with head and neck cancer both before and after treatment. We are interested in each individual's expectations and perceptions about their illness and treatment over the eight month period since diagnosis. If you participate, this may help us to find out what factors are important to people at different stages of their illness and treatment and why some people experience difficulty adjusting after their cancer diagnosis.
If you participate, a questionnaire pack will be used to assess your quality of life, anxiety and depression four times during the next twelve months. In addition, your views and expectations regarding your diagnosis and treatment will also be assessed by questionnaire.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive.

What will happen to me if I take part?

The study will last for 8 months from your consent to take part, and your participation will be required at 4 time periods during this period. 1) After diagnosis, but before treatment, 2) 1 month after treatment 3) at 4 months and 4) at 8 months following treatment. In order to help you fill in the questionnaire, a researcher will arrange to meet you at a time when you will be visiting the hospital for an appointment and at a time convenient to you. We would like you to complete a questionnaire pack asking about how you currently feel relating to your illness and your treatment. If at any time you change your mind and would like to withdraw from the study, you do not have to give us a reason.

What are the possible benefits of taking part?

The information we get from this study will help us to understand the issues that are important to newly diagnosed cancer patients and whether these issues change over time. This will enable us to be aware of any difficulties you are having throughout your treatment and follow-up at Guy's Hospital. We also hope that this information can be used to design appropriate interventions for individuals who have difficulty adjusting after cancer treatment. This should benefit patients in the future.

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it. Your identity will not be revealed in any report/publication.

Who is organising and funding the research?

This study is being funded by the Guy's & St. Thomas' Charitable Foundation and has been reviewed and approved by the Guy's Research Ethics Committee.

Contact for Further Information

Consumers for Ethics in Research (CERES) publish a leaflet entitled 'Medical Research and You': This leaflet gives more information about medical research and looks at some questions you may want to ask. Please ask us for a copy, or if you wish, a copy may be obtained from CERES, PO Box 1365, London N16 0BW.

If you have any queries, please do not hesitate to contact either the researcher or your treating consultant:

Carrie Llewellyn – Researcher
Psychology Unit;
5th Floor; Thomas Guy House,
Guy's Hospital,
London SE1 9RT
Tel: 020 7848 6790
Email: carrie.d.llewellyn@kcl.ac.uk

Professor Mark McGurk
Department of Oral & Maxillofacial Surgery
Guy's Tower,
Guy's Hospital,
London SE1 9RT
Tel: 020 7955 4342

Please keep this information sheet and a signed consent form for further reference.

APPENDIX VI: CONSENT FORM FOR PROSPECTIVE STUDY

Guy's, King's and St Thomas' Dental Institute
Department of Oral and Maxillofacial Surgery

Professor Mark McGurk MD FRCS DLO FDS RCS
Secretary
Tel 020 7955 4342

Floor 23 Guy's Tower
Guy's Hospital
London Bridge
London SE1 9RT
Tel 020 7955 4342
Fax 020 7955 4165

KING'S College LONDON

University of London

LREC Study Number: 02/03/07
Patient Identification Number for this trial:

APPENDIX VI

CONSENT FORM

Title of Project: Study of quality of life in patients treated for head and neck cancer

Name of Researchers: CD Llewellyn, Professor M McGurk, Professor J Weinman

Please initial box

1. I confirm that I have read and understand the information sheet (Version 3. dated 07/01/04) for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that sections of any of my medical notes may be looked at by responsible individuals from the research team or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐

4. I agree to take part in the above study. ☐

Name of Patient	Date	Signature

Researcher	Date	Signature

1 for patient; 1 for researcher; 1 to be kept with hospital notes

APPENDIX VII: QUESTIONNAIRE PACK FOR PROSPECTIVE STUDY

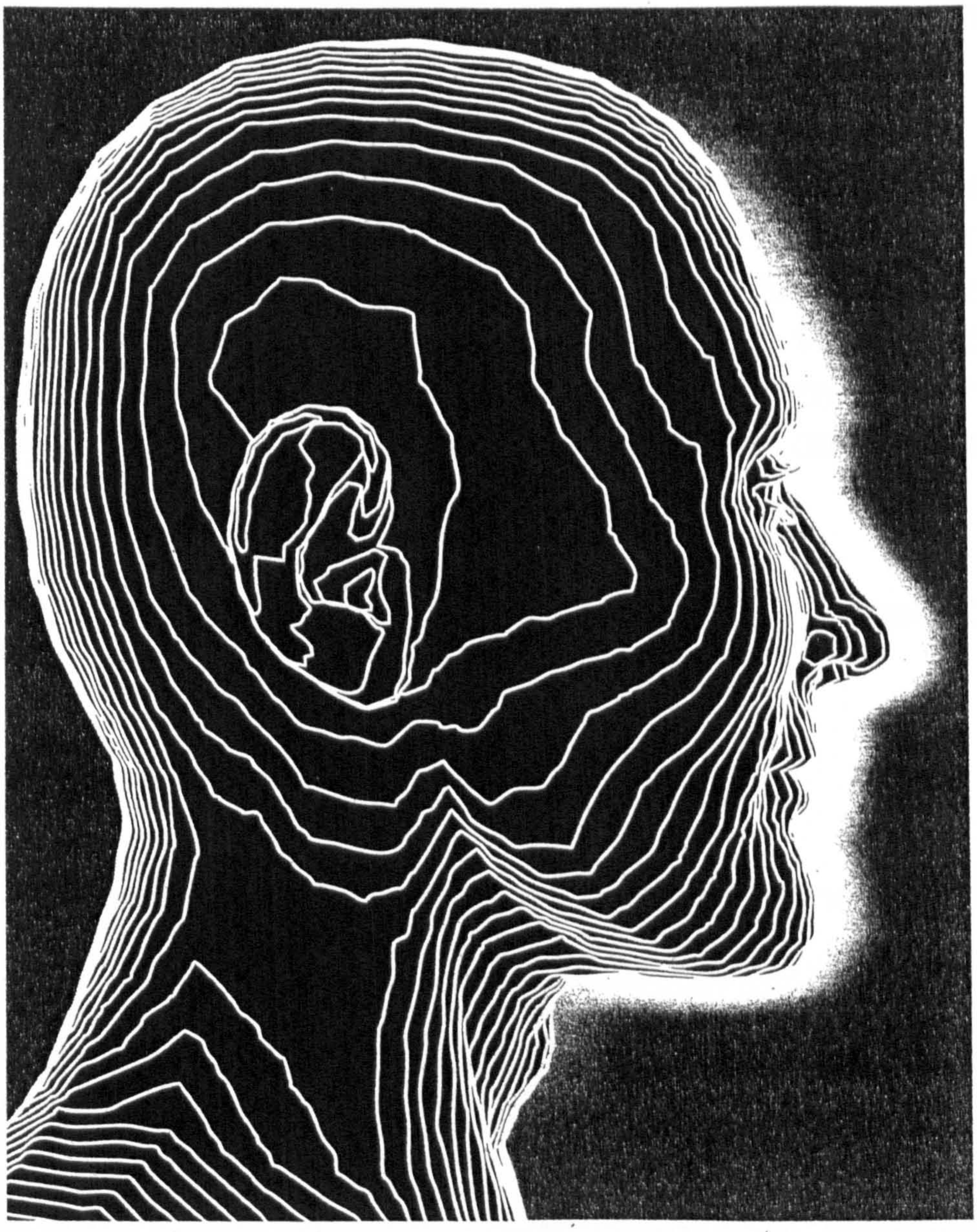
TEXT BOUND INTO

THE SPINE

APPENDIX VII

Patients' views

about cancer, treatment and informational requirements



Thank you for agreeing to take part in this study. By taking part you will be contributing to research which may be useful in improving the quality of life for patients in the future.

All of the information you provide will be completely confidential. None of the medical staff looking after you will see your answers.

Ref. No.

ABOUT THE QUESTIONNAIRE

Thank you for agreeing to take part in this study.

- The aim of this questionnaire is to find out what factors affect the quality of life of people who have been diagnosed with head and neck cancer. We are interested in the views you may have about your illness and its treatment over the next twelve months.

- The questionnaire starts with a section on your views about your illness and the treatment that has been recommended for you. The next section asks about your quality of life now and general health/activities. There are also questions asking about the way you are currently feeling. We would also like to find out your views regarding the information you have been given about your illness and treatment and finally there are some background questions about yourself

- Don't spend too long on any question - the first answer that comes to you is usually the best.

- Try to answer **all** the questions.

- If you cannot answer a question, don't worry, just go on to the next and return to it after.

- If you have difficulty answering these questions please contact the researcher contact details on the back of this questionnaire.

- **All the information you give will be treated in the strictest confidence. Your name will not be identified on this questionnaire and treating staff will not have access to your answers.**

- Once you have completed this questionnaire please return it in the enclosed freepost envelope or hand it directly to the researcher.

Please remember - there are no right or wrong answers. We are interested in your personal views only.

ILLNESS PERCEPTIONS QUESTIONNAIRE - REVISED (IPQ-R) &
BELIEFS ABOUT MEDICINES QUESTIONNAIRE (BMQ) - SPECIFIC SCALE

YOUR VIEWS ABOUT YOUR ILLNESS

Listed below are a number of symptoms that you may or may not have experienced since your illness. Please indicate by circling Yes or No, whether you have experienced any of these symptoms since your illness, and secondly, whether you believe that these symptoms are related to your illness.

Please fill in both sections

		I have experienced this symptom *since my illness*		This symptom is *related to my illness*	
S1	Pain	Yes	No	Yes	No
S2	Sore Throat	Yes	No	Yes	No
S3	Nausea	Yes	No	Yes	No
S4	Breathlessness	Yes	No	Yes	No
S5	Weight Loss	Yes	No	Yes	No
S6	Fatigue	Yes	No	Yes	No
S7	Stiff Joints	Yes	No	Yes	No
S8	Sore Eyes	Yes	No	Yes	No
S9	Difficulties eating	Yes	No	Yes	No
S10	Headaches	Yes	No	Yes	No
S11	Upset Stomach	Yes	No	Yes	No
S12	Sleep Difficulties	Yes	No	Yes	No
S13	Dizziness	Yes	No	Yes	No
S14	Loss of Strength	Yes	No	Yes	No
S15	Difficulties speaking	Yes	No	Yes	No

We are interested in your own <u>personal views</u> of how you now see your cancer. Please indicate how much you agree or disagree with the following statements about your cancer by <u>ticking the appropriate box</u>.

		Strongly Disagree	Disagree	Not sure	Agree	Strongly Agree
P1	My illness is likely to be permanent rather than temporary	☐	☐	☐	☐	☐
P2	My illness will last for a long time	☐	☐	☐	☐	☐
P3	I expect to have this illness for the rest of my life	☐	☐	☐	☐	☐

	Strongly Disagree	Disagree	Not sure	Agree	Strongly Agree
IP4 My illness has major consequences on my life	☐	☐	☐	☐	☐
IP5 My illness strongly affects the way others see me	☐	☐	☐	☐	☐
IP6 My illness causes difficulties for those who are close to me	☐	☐	☐	☐	☐
IP7R Nothing I do will affect my illness	☐	☐	☐	☐	☐
IP8 I have the power to influence my illness	☐	☐	☐	☐	☐
IP9R My actions will have no affect on the outcome of my illness	☐	☐	☐	☐	☐
IP10R My illness is a mystery to me	☐	☐	☐	☐	☐
IP11R I don't understand my illness	☐	☐	☐	☐	☐
IP12R My illness doesn't make any sense to me	☐	☐	☐	☐	☐
IP13 My symptoms come and go in cycles	☐	☐	☐	☐	☐
IP14 My illness is very unpredictable	☐	☐	☐	☐	☐
IP15 I go through cycles in which my illness gets better and worse.	☐	☐	☐	☐	☐
IP16 I get depressed when I think about my illness	☐	☐	☐	☐	☐
IP17 When I think about my illness I get upset	☐	☐	☐	☐	☐
IP18 Having this illness makes me feel anxious	☐	☐	☐	☐	☐

CAUSES OF YOUR ILLNESS

In the space below, please list in rank-order the three most important factors that you believe caused <u>YOUR illness</u>.

The most important causes for me:-

C1. _____

C2. _____

C3. _____

BELIEFS ABOUT TREATMENT

Please indicate how much you agree or disagree with the following statements about your treatment by ticking the appropriate box.

	Strongly Disagree	Disagree	Not sure	Agree	Strongly Agree
N1 My health in the future will depend on my treatment	☐	☐	☐	☐	☐
N2 My health at present depends on my treatment	☐	☐	☐	☐	☐
N3 My life would be impossible without this treatment	☐	☐	☐	☐	☐
N4 Without this treatment I would be very ill	☐	☐	☐	☐	☐
N5 My treatment protects me from becoming worse	☐	☐	☐	☐	☐
C1 Having to undergo treatment worries me	☐	☐	☐	☐	☐
C2 I sometimes worry about the long-term effects of the treatment	☐	☐	☐	☐	☐
C3 My treatment is a mystery to me	☐	☐	☐	☐	☐
C4 My treatment disrupts my life	☐	☐	☐	☐	☐

THE EUROPEAN ORGANISATION FOR RESEARCH AND TREATMENT OF CANCER (EORTC) QLQ - C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

		Not at All	A Little	Quite a Bit	Very Much
QLQ1	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
QLQ2	Do you have any trouble taking a long walk?	1	2	3	4
QLQ3	Do you have any trouble taking a short walk outside of the house?	1	2	3	4
QLQ4	Do you need to stay in bed or a chair during the day?	1	2	3	4
QLQ5	Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:

QLQ6	Were you limited in doing either your work or other daily activities?	1	2	3	4
QLQ7	Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
QLQ8	Were you short of breath?	1	2	3	4
QLQ9	Have you had pain?	1	2	3	4
QLQ10	Did you need to rest?	1	2	3	4
QLQ11	Have you had trouble sleeping?	1	2	3	4
QLQ12	Have you felt weak?	1	2	3	4
QLQ13	Have you lacked appetite?	1	2	3	4
QLQ14	Have you felt nauseated?	1	2	3	4
QLQ15	Have you vomited?	1	2	3	4

During the past week:

	Not at All	A Little	Quite a Bit	Very Much
QLQ16 Have you been constipated?	1	2	3	4
QLQ17 Have you had diarrhoea?	1	2	3	4
QLQ18 Were you tired?	1	2	3	4
QLQ19 Did pain interfere with your daily activities?	1	2	3	4
QLQ20 Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
QLQ21 Did you feel tense?	1	2	3	4
QLQ22 Did you worry?	1	2	3	4
QLQ23 Did you feel irritable?	1	2	3	4
QLQ24 Did you feel depressed?	1	2	3	4
QLQ25 Have you had difficulty remembering things?	1	2	3	4
QLQ26 Has your physical condition or medical treatment interfered with your <u>family</u> life?	1	2	3	4
QLQ27 Has your physical condition or medical treatment interfered with your <u>social</u> activities?	1	2	3	4
QLQ28 Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

QLQ29 How would you rate your <u>overall health</u> during the past week?

1	2	3	4	5	6	7
Very poor						**Excellent**

QLQ30 How would you rate your <u>overall quality of life</u> during the past week?

1	2	3	4	5	6	7
Very poor						**Excellent**

THE EUROPEAN ORGANISATION FOR RESEARCH AND TREATMENT OF CANCER HEAD AND NECK MODULE (EORTC QLQ - H&N35)

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you.

During the past week:	**Not at All**	**A Little**	**Quite a Bit**	**Very Much**
HN31 Have you had pain in your mouth?	1	2	3	4
HN32 Have you had pain in your jaw?	1	2	3	4
HN33 Have you had soreness in your mouth?	1	2	3	4
HN34 Have you had a painful throat?	1	2	3	4
HN35 Have you had problems swallowing liquids?	1	2	3	4
HN36 Have you had problems swallowing pureed food?	1	2	3	4
HN37 Have you had problems swallowing solid food?	1	2	3	4
HN38 Have you choked when swallowing?	1	2	3	4
HN39 Have you had problems with your teeth?	1	2	3	4
HN40 Have you had problems opening your mouth wide?	1	2	3	4
HN41 Have you had a dry mouth?	1	2	3	4
HN42 Have you had sticky saliva?	1	2	3	4
HN43 Have you had problems with your sense of smell?	1	2	3	4
HN44 Have you had problems with your sense of taste?	1	2	3	4
HN45 Have you coughed?	1	2	3	4
HN46 Have you been hoarse?	1	2	3	4
HN47 Have you felt ill?	1	2	3	4
HN48 Has your appearance bothered you?	1	2	3	4
HN48* Have you had any problems in the area of your shoulder/arm e.g. pain or mobility problems?	1	2	3	4

During the past week:	Not at All	A Little	Quite a Bit	Very Much
HN49 Have you had trouble eating?	1	2	3	4
HN50 Have you had trouble eating in front of your family?	1	2	3	4
HN51 Have you had trouble eating in front of other people?	1	2	3	4
HN52 Have you had trouble enjoying your meals?	1	2	3	4
HN53 Have you had trouble talking to other people?	1	2	3	4
HN54 Have you had trouble talking on the telephone?	1	2	3	4
HN55 Have you had trouble having social contact with your family?	1	2	3	4
HN56 Have you had trouble having social contact with friends?	1	2	3	4
HN57 Have you had trouble going out in public?	1	2	3	4
HN58 Have you had trouble having physical contact with family or friends?	1	2	3	4
HN59 Have you felt less interest in sex?	1	2	3	4
HN60 Have you felt less sexual enjoyment?	1	2	3	4

During the past week:	No	Yes
HN61 Have you used pain-killers?	1	2
HN62 Have you taken any nutritional supplements (excluding vitamins)?	1	2
HN63 Have you used a feeding tube?	1	2
HN64 Have you lost weight?	1	2
HN65 Have you gained weight?	1	2

SF-12 HEALTH SURVEY (SF-12v2)

YOUR HEALTH AND WELL-BEING

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

For each of the following questions please mark an [X] in the box that best describes your answer.

SF1 In general would you say your health is:

Excellent	Very good	Good	Fair	Poor
❑	❑	❑	❑	❑

SF2 The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so how much?

	Yes limited a lot	**Yes limited a little**	**No, not limited at all**
a. <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	❑	❑	❑
b. climbing <u>several</u> flights of stairs	❑	❑	❑

SF3 During the past <u>4 weeks</u> how much time have you had any of the following problems with your work or regular daily activities <u>as a result of your **physical health**</u>?

	All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a. <u>Accomplished</u> less than you would like	❑	❑	❑	❑	❑
b. Were limited in the <u>kind</u> of work or other activities	❑	❑	❑	❑	❑

SF4 During the <u>past 4 weeks</u> how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any **emotional problems**</u> (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. <u>Accomplished less</u> than you would like	❑	❑	❑	❑	❑
b. Did work or other activities <u>less carefully</u> than usual	❑	❑	❑	❑	❑

SF5 During the <u>past 4 weeks</u> how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
❑	❑	❑	❑	❑

SF6 These questions are about how you feel and how things have been with you <u>during the past 4 weeks.</u> For each question, please give one answer that comes closest to the way you have been feeling. How much of the time <u>during the last 4 weeks</u>...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Have you felt calm and peaceful	❑	❑	❑	❑	❑
b. Did you have a lot of energy	❑	❑	❑	❑	❑
c. Have you felt downhearted and depressed	❑	❑	❑	❑	❑

SF7 During the <u>past 4 weeks</u> how much of the time has your <u>**physical health or emotional problems**</u> interfered with your social activities (like visiting friends, relative, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
❑	❑	❑	❑	❑

THE PATIENT GENERATED INDEX (PGI)

A PATIENT GENERATED INDEX OF QUALITY OF LIFE

Your answers to the following steps will tell us how your life is affected by your cancer and treatment. It will also tell us how you would like to see your life improve

STEP 1: Identifying Areas

We would like you to think of the **most important areas** of your life that are affected by your cancer and treatment. please write up to five areas in the boxes below.

Here are some areas other patients have mentioned that might help you to think how your life has been affected:

Social life, ability to work, housework, hobbies, interests, makes me moody, lose of independence, can't go shopping, walking, climbing stairs, sitting, sleep, tiredness, social life, ability to look after children/grand-children, other peoples reactions, fear of recurrence, feeling uncertain, difficulty eating, family life, lack of confidence, panic attacks, loss of motivation, concern over future, feeling dependent on others, letting people down, low self-esteem, pain, sex-life, etc.

Try to think of areas that are affected most and are the most important to you.

1.
2.
3.
4.
5.

AREAS AFFECTED BY OTHER HEALTH PROBLEMS

ALL OTHER NON-HEALTH AREAS OF LIFE

STEP 2: Scoring each area

In this part we would like you to score **the areas you mentioned in step 1**. This score should show how **badly affected you were over the past month**. Please score each area out of 10 using this scale:

10 = Exactly as you would like to be
9 = Close to how you would like to be
8 = Very good but not how you would like to be
7 = Good, but not how you would like to be
6 = Between good and fair
5 = Fair
4 = Between poor and fair
3 = Poor, but not the worst you could imagine
2 = Very poor but not the worst you could imagine
1 = Close to the worst you could imagine
0 = The worst you could imagine

Please use the last two boxes to score all areas affected by other health problems and all other non-health areas of life

STEP 3: Spending points

We want you to imagine that any or all of the areas of your life could be improved. You have 14 imaginary points to spend to show which areas you would most like to see improve. Spend more points on areas you would most like to improve and less on areas that are not so important. You don't have to spend points in every area. **You can't spend more than 14 points in total.**

Remember the total must add up to 14

SATISFACTION WITH CANCER INFORMATION PROFILE (SCIP)

TEXT BOUND INTO

THE SPINE

Satisfaction with information

We would like to ask you about the information you have received about you diagnosis and treatment for cancer. Firstly, please answer whether you have received *any* information about the following aspects of your illness and secondly, rate the amount you have received (if Applicable). If you are having or have had more than one type of treatment please give your overall feeling about the information you have received.

Please tick one box on each section	Did you receive *any* information about:		Do you feel as if you have *received enough* information			
	Yes	No	Too much	About right	Too little	None wanted
11 What your diagnosis means to you	❑	❑	❑	❑	❑	❑
12 The types of treatment suitable for you	❑	❑	❑	❑	❑	❑
13 The expected benefit of treatment	❑	❑	❑	❑	❑	❑
14 What procedures your treatment will involve	❑	❑	❑	❑	❑	❑
15 Whether the treatment has any unwanted side effects	❑	❑	❑	❑	❑	❑
16 What the risks of you experiencing side effects are	❑	❑	❑	❑	❑	❑
17 What the risks of you experiencing complications are	❑	❑	❑	❑	❑	❑
18 What you should do if you experience unwanted side effects	❑	❑	❑	❑	❑	❑
19 Whether your treatment interferes with other medicines you may be taking	❑	❑	❑	❑	❑	❑
110 How you may expect to feel immediately after treatment	❑	❑	❑	❑	❑	❑
111 The effects of treatment on your ability to work	❑	❑	❑	❑	❑	❑
112 Who to ask/where to go for possible financial support	❑	❑	❑	❑	❑	❑
113 Whether you may need further treatment in the future	❑	❑	❑	❑	❑	❑

Please tick one box on each section

	Did you receive *any* information about:		Do you feel as if you have *received enough* information			
	Yes	No	Too much	About right	Too little	None wanted
I14 The effect of treatment on your appearance	❑	❑	❑	❑	❑	❑
I15 The long term impact of treatment on functioning (daily activities)	❑	❑	❑	❑	❑	❑
I16 How long you expect recovery to take	❑	❑	❑	❑	❑	❑
I17 How your treatment may impact on your quality of life over the next year	❑	❑	❑	❑	❑	❑
I18 Patient support groups for you and your partner	❑	❑	❑	❑	❑	❑

Overall, how would you rate the following:

	Very satisfied	Satisfied	Neither	Dis-satisfied	Very dis-satisfied
I19 The usefulness of the information to you	❑	❑	❑	❑	❑
I20 The usefulness of the information to your partner/family	❑	❑	❑	❑	❑
I21 The amount of written information supplied	❑	❑	❑	❑	❑
I22 The amount of verbal information supplied	❑	❑	❑	❑	❑
I23 The timing at which you received information	❑	❑	❑	❑	❑
I24 The detail of the information given to you	❑	❑	❑	❑	❑
I25 How understandable the information was to you	❑	❑	❑	❑	❑

I26 Is there any further information you wish you had received?

I27 Is there anything else you would like to add regarding the information you received?

THE HOSPITAL ANXIETY AND DEPRESSION SCALE (HADS)

This section will help you to let us know how you are. Read each item and tick the box of the response which comes closest to how <u>you have felt in the last few days</u>. Don't take too long over your replies, your immediate reaction will probably be more accurate than a long thought out response.

AD1 **I feel tense or 'wound up'**

- Most of the time ☐
- A lot of the time ☐
- From time to time, occasionally ☐
- Not at all ☐

AD2 **I still enjoy the things I used to enjoy**

- Definitely as much ☐
- Not quite so much ☐
- Only a little ☐
- Hardly at all ☐

AD3 **I get a sort of frightened feeling like 'butterflys' in my stomach**

- Not at all ☐
- Occasionally ☐
- Quite often ☐
- Very often ☐

AD4 **I get a sort of frightened feeling as if something awful is about to happen**

- Very definitely and quite badly ☐
- Yes, but not too badly ☐
- A little, but it doesn't worry me ☐
- Not at all ☐

AD5 **I have lost interest in my appearance**

- Definitely ☐
- I don't take so much care as I should ☐
- I may not take quite as much care ☐
- I take just as much care as ever ☐

AD6 **I can laugh and see the funny side of things**

- As much as I always could ☐
- Not quite so much now ☐
- Definitely not so much now ☐
- Not at all ☐

AD7 **I feel restless as if I have to be on the move**

- Very much indeed ☐
- Quite a lot ☐
- Not very much ☐
- Not at all ☐

AD8 **Worrying thoughts go through my mind**

- A great deal of the time ☐
- A lot of the time ☐
- From time to time but not too often ☐
- Only occasionally ☐

HAD9 I look forward with enjoyment to things

- As much as I ever did ☐
- Rather less than I used to ☐
- Definitely less than I used to ☐
- Hardly ever ☐

HAD10 I feel cheerful

- Not at all ☐
- Not often ☐
- Sometimes ☐
- Most of the time ☐

HAD11 I get sudden feeling of panic

- Very often Indeed ☐
- Quite often ☐
- Not very often ☐
- Not at all ☐

HAD12 I can sit at ease and feel relaxed

- Definitely ☐
- Usually ☐
- Not often ☐
- Not at all ☐

AD13 I can enjoy a good book or radio or TV programme

- Often ☐
- Sometimes ☐
- Not often ☐
- Very seldom ☐

AD14 I feel as if I am slowed down

- Nearly all the time ☐
- Very often ☐
- Sometimes ☐
- Not at all ☐

FOR Over the past month, how often have you worried about the possibility that cancer might come back?

- None of the time ☐
- Rarely ☐
- Occasionally ☐
- Often ☐
- All the time ☐

THE BRIEF COPE

These next items deal with ways you've been coping with the stress in your life since you were diagnosed with cancer. There are many ways to try to deal with problems. Different people deal with things in different ways, but I'm interested in how you've tried to deal with it. Each item says something about a particular way of coping. I want to know to what extent you have been doing what the item says. How much or how frequently. Don't answer on the basis of whether it seems to be working or not—just whether or not you're doing it. Use these response choices. Try to rate each item separately in your mind from the others. Make your answers as true FOR YOU as you can.

	I havn't been doing this at all	I've been doing this a little bit	I've been doing this a medium amount	I've been doing this a lot
CO1 I've been turning to work or other activities to take my mind off things.	☐	☐	☐	☐
CO2 I've been concentrating my efforts on doing something about the situation I'm in.	☐	☐	☐	☐
CO3 I've been saying to myself "this isn't real."	☐	☐	☐	☐
CO4 I've been using alcohol or other drugs to make myself feel better.	☐	☐	☐	☐
CO5 I've been getting emotional support from others.	☐	☐	☐	☐
CO6 I've been giving up trying to deal with it.	☐	☐	☐	☐
CO7 I've been taking action to try to make the situation better.	☐	☐	☐	☐
CO8 I've been refusing to believe that it has happened.	☐	☐	☐	☐
CO9 I've been saying things to let my unpleasant feelings escape.	☐	☐	☐	☐
CO10 I've been getting help and advice from other people.	☐	☐	☐	☐
CO11 I've been using alcohol or other drugs to help me get through it.	☐	☐	☐	☐

	I haven't been doing this at all	I've been doing this a little bit	I've been doing this a medium amount	I've been doing this a lot
co12 I've been trying to see it in a different light, to make it seem more positive.	☐	☐	☐	☐
co13 I've been criticising myself.	☐	☐	☐	☐
co14 I've been trying to come up with a strategy about what to do.	☐	☐	☐	☐
co15 I've been getting comfort and understanding from someone.	☐	☐	☐	☐
co16 I've been giving up the attempt to cope.	☐	☐	☐	☐
co17 I've been looking for something good in what is happening.	☐	☐	☐	☐
co18 I've been making jokes about it.	☐	☐	☐	☐
co19 I've been doing something to think about it less, such as going to movies, watching TV, reading, daydreaming, sleeping, or shopping.	☐	☐	☐	☐
co20 I've been accepting the reality of the fact that it has happened.	☐	☐	☐	☐
co21 I've been expressing my negative feelings.	☐	☐	☐	☐
co22 I've been trying to find comfort in my religion or spiritual beliefs.	☐	☐	☐	☐
co23 I've been trying to get advice or help from other people about what to do.	☐	☐	☐	☐
co24 I've been learning to live with it.	☐	☐	☐	☐
co25 I've been thinking hard about what steps to take.	☐	☐	☐	☐
co26 I've been blaming myself for things that happened.	☐	☐	☐	☐
co27 I've been praying or meditating.	☐	☐	☐	☐
co28 I've been making fun of the situation.	☐	☐	☐	☐

LIFE ORIENTATION TEST – REVISED (LOT-R)

Please be as honest and accurate as you can throughout. Try not to let your response to one statement influence your responses to other statements. There are no "correct" or "incorrect" answers. Answer according to your own feelings, rather than how you think "most people" would answer.

	I agree a lot	I agree a little	Neither	I Disagree a little	I disagree a lot
LOT1 In uncertain times, I usually expect the best.	☐	☐	☐	☐	☐
LOT2 If something can go wrong for me, it will.	☐	☐	☐	☐	☐
LOT3 I'm always optimistic about my future.	☐	☐	☐	☐	☐
LOT4 I hardly ever expect things to go my way.	☐	☐	☐	☐	☐
LOT5 I rarely count on good things happening to me.	☐	☐	☐	☐	☐
LOT6 Overall, I expect more good things to happen to me than bad.	☐	☐	☐	☐	☐

BACKGROUND QUESTIONS ABOUT YOU

We would like to ask you a few questions about yourself.

Your date of birth _____

Are you: **MALE** ❑

FEMALE ❑

Please tick the box that best describes your highest educational qualification:

No qualifications ❑

GCSE / O levels ❑

GCE / A levels or similar ❑

Higher Education or similar ❑

Degree or similar ❑

Higher degree ❑

Other, please specify _____

Are you...?

Single	❑	**Married/living together**	❑
Divorced	❑	**Widowed**	❑
Separated	❑		

How would you describe your ethnic group?

White	❑	**Indian**	❑
Black - Caribbean	❑	**Pakistani**	❑
Black - African	❑	**Bangladeshi**	❑
Black - Other	❑	**Chinese**	❑
Other	❑	**Other Asian**	❑

Thank you for your time and effort.

Please check that you have answered all the questions on each page.

Return in the pre-paid envelope.

APPENDIX VIII: PATIENT INFORMATION LETTER FOR CROSS-SECTIONAL STUDY

Guy's, King's and St Thomas' Dental Institute
Department of Oral and Maxillofacial Surgery

Professor Mark McGurk MD FRCS DLO FDS RCS
Secretary
Tel 020 7955 4342

Floor 23 Guy's Tower
Guy's Hospital
London Bridge
London SE1 9RT
Tel 020 7955 4342
Fax 020 7955 4165

KING'S College LONDON

University of London

APPENDIX VIII

PATIENT INFORMATION SHEET Version 1

Study of quality of life in patients treated for conditions of the salivary gland

Dear

We are a research team at Guy's Hospital, London who are carrying out a study examining the quality of life of patients who have been treated for conditions of the salivary gland. We would like to invite you to help us with our research. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

What is the purpose of the study?

We would like to find out what factors affect the post-treatment quality of life of people with conditions of the salivary gland. We are interested in each individual's experience and satisfaction with their life since treatment. If you participate, this may help us to find out what factors are important to people after being treated for their illness and why some people experience difficulty adjusting after treatment.

If you participate, the enclosed questionnaire pack will be used to assess your current quality of life and other related factors.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive.

What will happen to me if I take part?

This study will require you to complete the questionnaire pack once. If you require any help completing the questionnaire, please let us know and a researcher will arrange to meet you at a time when you will be visiting the hospital for an appointment or at home at a time convenient to you. If at any time you change your mind and would like to withdraw from the study, you do not have to give us a reason.

What are the possible benefits of taking part?

The information we get from this study will help us to understand the issues that are important to patients who have undergone treatment for cancer and whether these issues change over time. We also hope that this information can be used to design appropriate interventions for individuals who have difficulty adjusting after cancer treatment. This should benefit patients in the future.

Will my taking part in this study be kept confidential?

All information which is collected about you during this study will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it. Your identity will not be revealed in any report/publication. If you do not wish to complete the questionnaire please return it in the reply-paid envelope and this will ensure we do not inadvertently ask you again.

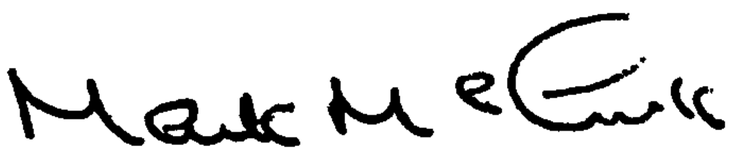
Who is organising and funding the research?

This study is being funded by the Guy's & St. Thomas' Charitable Foundation and has been reviewed and approved by South East London NHS Research Ethics Committee.

Contact for Further Information

Consumers for Ethics in Research (CERES) publish a leaflet entitled 'Medical Research and You'. This leaflet gives more information about medical research and looks at some questions you may want to ask. Please ask us for a copy, or if you wish, a copy may be obtained from CERES, PO Box 1365, London N16 0BW.

Yours sincerely,



Professor Mark McGurk

If you have any queries, please do not hesitate to contact either myself (Tel: 020 7955 4342) or Carrie Llewellyn (020 7848 6790).

Please keep this information sheet and a signed consent form for further reference.

APPENDIX IX: CONSENT FORM FOR CROSS-SECTIONAL STUDY

Guy's, King's and St Thomas' Dental Institute
Department of Oral and Maxillofacial Surgery

Professor Mark McGurk MD FRCS DLO FDS RCS
Secretary
Tel 020 7955 4342

Floor 23 Guy's Tower
Guy's Hospital
London Bridge
London SE1 9RT
Tel 020 7955 4342
Fax 020 7955 4165

KING'S College LONDON

University of London

LREC Study Number: 02/03/07
Patient Identification Number for this trial:

APPENDIX IX

CONSENT FORM

Title of Project: Study of quality of life in patients treated for conditions of the salivary glands

Name of Researchers: CD Llewellyn, Professor M McGurk, Professor J Weinman

Please Initial box

1. I confirm that I have read and understand the information sheet (Version 1. dated 07/01/04) for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that sections of any of my medical notes may be looked at by responsible individuals from the research team or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐

4. I agree to take part in the above study. ☐

Name of Patient	Date	Signature
Researcher	Date	Signature

1 for patient; 1 for researcher; 1 to be kept with hospital notes

APPENDIX X: LREC LETTERS OF APPROVAL

APPENDIX X

King's College Hospital NHS

NHS Trust

Carrie Llewellyn
GKTSM
Psychology Unit
5th Floor Thomas Guy House
Guy's Campus
London
SE1 9RT

King's College Hospital
Denmark Hill
London SE5 9RS

Tel: 020 7737 4000
Fax: 020 7346 3445
www.kingsch.nhs.uk

3rd February 2003

Dear Carrie Llewellyn

Re.: King's College Hospital LREC Protocol No. 02-03-053
Guy's LREC Protocol No. 02/03/07
Assessing the role of psychological factors in predicting subjective quality of life in patients with head and neck cancer

Thank you for submitting the above application. This is suitable for approval under the reciprocal arrangement of the Ethics Committees within Southeast London Strategic Health Authority. The following documents have been reviewed:

- Health Authority Locality Form signed 17.01.03
- Guy's LREC application form signed 22.02.02
- Guy's LREC approval letter dated 18.04.02
- Guy's and St Thomas' R&D registration confirmation letter dated 25.04.02
- Consent Form referring to information sheet version 2 dated 04.04.02
- Patient Information Sheet version 2 dated 04.04.02
- Research Protocol version 1 * (* version number allocated by KCH LREC as none given)
- CV for Andrew John Lyons

I have no 'local' ethical objections to this study and therefore I am happy to give approval on the understanding that you will follow the conditions of approval set out below.

- You do not undertake this research until approval has been given by the relevant NHS Trust.

- You do not deviate from, or make changes to, the protocol without prior written approval from this Research Ethics Committee, except where necessary to eliminate immediate hazards to research participants or when the change involves only logistical or administrative aspects of the research. In such cases the REC should be informed within seven days of the implementation of the change.

- You complete and return the standard progress report form to the REC one-year from the date on this letter and thereafter on an annual basis. This form should also be used to notify the REC when you research is completed and in this case should be sent to this REC within three months of completion.

- If you decide to terminate this research prematurely you send a report to this REC within 15 days, indicating the reason for early termination.

- You advise the REC of any unusual or unexpected results that raise questions about the safety of the research

King's College Hospital LREC complies with the ICH GCP requirements.

Yours sincerely

L G Strittmatter

p.p. **Dr D Jewitt**
Chairman, Research Ethics Committee
King's College Hospital

Contact: Lisa Strittmatter
Tel: 020 7346 3923
Fax: 020 7346 4245
Email: lisa.strittmatter@kingsch.nhs.uk

Guy's & St Thomas'

HOSPITAL TRUST

Guy's Research Ethics Committee

Chairman: Professor Steven Sacks
Administrator: Mrs Valerie Heard
valerie.heard@gstt.sthames.nhs.uk

Guy's Research Ethics Committee
3rd Floor Nuffield Annexe
Henriette Raphael House
Guy's Hospital
London SE1 9RT

Tel: 020 7955 4559 or 020 7955 5000 Ext. 5181
Fax: 020 7955 4303

12 March 2003
Ref: 02/03/07

Please always quote reference number in correspondence

Ms Carrie Llewellyn
Unit of Psychology
5th Floor Thomas Guy House
Guy's Hospital

Dear Ms Llewellyn

Re: 02/03/07 Assessing the role of psychological factors in predicting subjective quality of life in patients with head and neck cancer
Amendments I and II (Version 1) detailed in form dated 3 March 2003
Life Orientation Test (undated)
Appendix 2. The satisfaction with information about medicines scale (SIMS) (undated)

An Executive Sub-Committee of the Guy's Research Ethics Committee met on 10 March 2003 to consider the above amendment(s) and gave approval on behalf of the Committee. This will be reported in the minutes for the meeting held on 26 March 2003

This Committee functions in accordance with the guidelines of ICH GCP. A list of the full membership of the Guy's Research Ethics Committee is given below.

Yours sincerely

Valerie Heard

Mrs Valerie Heard
LREC Administrator

Full membership of the Guy's Research Ethics Committee

Professor Steven Sacks, Chairman, Professor of Nephrology	
Miss Sarah Allen	Department of Nuclear Medicine, Guy's
Miss Sara Arenas-Lopez	Pharmacist
Miss Lisa Burnapp	Nursing Representative, Guy's
Dr Michael Fenlon	Prosthetic Dentistry, Guy's
Mr John Fowler	Lay Representative, non-Guy's
Anna McKay	Legal/Lay Member
Dr David Miles	Consultant Oncologist, Guy's
Dr Jacques Mizan	Academic Assistant GP Member, non-Guy's
Professor Costantino Pitzalis	Consultant Rheumatologist, Guy's
Mrs Ruth Sanderson	Lay Member, Teacher
Dr M.K. Sharief	Consultant Neurologist
Professor Emily Simonoff	Professor of Child & Adolescent Psychiatry, Guy's
Jin-Jin Tang	Pharmacist
Dr Shane Tibby	Paediatric Intensive Care Unit, Guy's
Dr Val Wass	Senior Lecturer in General Practice & Primary Care
Dr Adrian Williams and Dr Adrian Hopper, Co-Chairs St Thomas' Hospital LREC, ex officio members	

Guy's & St Thomas'

HOSPITAL TRUST

Guy's Research Ethics Committee
Chairman: Professor Steven Sacks
Administrator: Mrs Valerie Heard

Guy's Research Ethics Committee
Guy's Hospital
London SE1 9RT

Tel: 020 7955 5000 Extension 5181
Fax: 020 7955 4303
valerie.heard@kcl.ac.uk

18 April 2002
02/03/07

Ms Carrie Llewellyn
Department of Oral Medicine
King's College Dental Institute
Denmark Hill Campus
Caldecot Road
London SE5 9RW

Dear Ms Llewellyn

Re: 02/03/07 Assessing the role of psychological factors in predicting subjective quality of life in patients with head and neck cancer
Patient information sheet and consent form Version 2 dated 04/04/02
Questionnaire EORTC QLQ-C30 (version 3)
PROFESSOR JOHN WEINMAN, PROFESSOR MARK MCGURK (SUPERVISORS)

Thank you for your letter of 4th April 2002 enclosing an amended information sheet and consent form listed above. This meets the committee's concerns and the study has Guy's Research Ethics Committee approval.

All information sheets and consent forms in this study need to carry the Ethics Committee reference number and version number/date.

Permission is granted on the understanding that:

i) Any ethical problem arising in the course of the project will be reported to the Committee;

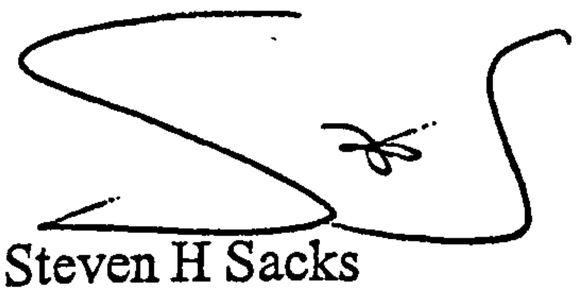
ii) Any change in the protocol or subsequent protocol amendments will be forwarded to the Committee using the enclosed form (available in electronic format). The principal investigator should see and approve any such changes and this needs to be indicated in the forwarding letter to the Committee.

iii) A brief report will be submitted one year after commencement, thereafter annually, and after completion of the study. Continuing approval is dependent upon this report.

iv) Approval is given for research to start within 12 months of the date of application. If the start is delayed beyond this time, applicants are required to consult the Chairman of the Committee. **If the study does not start within 3 months of date of this letter, please notify the Committee of the date of commencement for record purposes.**

A list of members in attendance at the 27 March 2002 meeting is enclosed.

Yours sincerely



Steven H Sacks
Chairman of the Guy's Hospital Research Ethics Committee

Brighton and Hove City NHS
Primary Care Trust

6th Floor
Vantage Point
New England Road
Brighton
BN1 4GW

Direct Line: 01273 296437
✉ kerry.longhurst@bhcpct.nhs.uk

19 August 2003

Carrie Llewellyn
Psychology Unit
5th Floor
Thomas Guy House
Guy's Hospital
London
SE1 9RT

Ref: (B) 03/10
From the Brighton LREC

Dear Carrie

Study title: **Assessing the Role of Psychological Factors in Predicting Subjective Quality of Life (QoL) in Patients with Head and Neck Cancer**

- **Patient information sheet (version 4 - dated 13/8/03)**
- **Consent form (version 3 - dated 1/7/03)**
- **Research Protocol (dated 13/5/03)**

Thank you for your letter and enclosure of 13 August 2003.

I can confirm that the amended patient information sheet is now satisfactory and I am writing to inform you that Chairman's Action has been given to **approve** this study.

Approval is granted on the understanding that:

i) Any ethical problem arising in the course of the project will be reported to the Committee.
ii) Any change in the protocol or subsequent protocol amendments will be forwarded to the LREC. The principal investigator should see and approve any such changes and this needs to be indicated in the forwarding letter to the Committee.
iii) All serious adverse events must be reported within one week to the Ethics Committee, at the same time indicating that the principal investigator has seen the report and whether or not they feel it poses any new ethical or safety issues.
iv) A brief report will be submitted one year after commencement, thereafter annually, and after completion of the study.
v) Approval is given for research to start within 12 months of the date of application. If the start is delayed beyond this time, applicants are required to consult the Chairman of the Committee.

Brighton & Sussex University Hospitals NHS Trust now operates a research & development approvals process. If you are an employee of the Trust, or wish to undertake research using either Trust patients or facilities you will need to apply for trust approval before the project can commence. In order to do this you will need to complete and sign a Trust approval project record. To obtain a copy, please contact Scott Harfield, R&D Manager on 01273 696955 ext 7497 or email scott.harfield@bsuh.nhs.uk.

Yours sincerely

Kerry Longhurst (Mrs)
Senior Research Ethics Committee Administrator

C:\Program Files\Qualcomm\Eudora\(b)0310d.doc

South East London NHS
Strategic Health Authority

University Hospital Lewisham
Research Ethics Committee
1st Floor Research Centre
Lewisham High Street
London, SE13 6LH

Chair: Annette Jeanes
Administrator: Pat Martin
Direct line: 020 8333 3135
Fax: 020 8314 0626

Email: pat.martin@uhl.nhs.uk
Website: www.corec.org.uk

29th July 2003

Ms Carrie Llewellyn
Psychology Unit
Giy's, King's & St Thomas' School of Medicine
5th Floor Thomas Guy House
Guy's Campus
London Bridge
SE1 9RT

Dear Ms Llewellyn,

Protocol: **Assessing the role of psychological factors in predicting subjective quality of life in patients with head and neck cancer**

Ref No: **03/08/01** (*please quote in all correspondence*)

Thank you for your application. This study has been approved under reciprocal agreements made with the Guys' & St Thomas' Hospital Ethics Committee.

Yours sincerely,

Pat Martin

cc Annette Jeanes
Chair, Lewisham REC

Patron Her Majesty The Queen

THE ROYAL MARSDEN NHS TRUST

LONDON AND SURREY

Ref: CF/Ethics/ PROTOCOL No. 2300

27 August 2003

Ms Carrie Llewellyn
Research Psychologist
Psychology Unit
5th Floor, Thomas Guy House
Guy's Hospital
LONDON SE1 9RT

Dear Carrie

Re: Protocol No. 2300 Assessing the role of psychosocial factors in predicting subjective quality of life (QoL) in patients with head and neck cancer
Dr Christopher Nutting, Ms Carrie Llewellyn, Ms Joanna Coetzer)

Thank you for sending me the revised patient information sheet (Version 2) for the above study incorporating the changes requested by the Research Ethics Committee at their meeting on 20th August 2003. I confirm that this now meets the Committee's requirements and that final approval is given for the study to go ahead.

Please note the following:

1. Ethical approval is granted subject to commencement within one year of the date of this letter. If for any reason it is not possible to start within one year, ethical approval will be deemed to have lapsed at the end of the period and it will be necessary to resubmit the proposal to the Committee for approval.

2. The REC is required by its Constitution and Terms of Reference to monitor the progress of approved research and requires you to meet the following ongoing obligations:

(a) to submit to the REC any proposed amendments to the research protocol for consideration and approval prior to any implementation

(b) to inform the REC of any adverse events (or any other relevant information notified to the Consultant in charge or of which he/she becomes aware) relating to the original application or amendments submitted to the REC and/or which would raise questions about the ethical acceptability of the continued conduct of the research

(c) to provide for the REC an annual report on the progress of research projects

(d) to supply to the REC copies of any papers published as a result of research

(e) to inform the REC before publishing any unanticipated and/or sensitive research results

(f) to inform the REC of any anticipated/actual adverse media reports, wherever possible prior to their publication/transmission.

The Royal Marsden NHS Trust Research Ethics Committee is compliant with the International Committee on Harmonisation/Good Clinical Practice (ICH/GCP) Guidelines for the Conduct of Trials involving the Participation of Human Subjects as they relate to the responsibilities, composition, function, operations and records of an Independent Committee/Independent Review Board. To this end it undertakes to adhere as far as is consistent with its Constitution, to the relevant clauses of the ICH Harmonised Tripartite Guideline for Good Clinical Practice, adopted by the Commission of the European Union on 17 January 1997.

Yours sincerely

CAFerguson

Christine A Ferguson
Secretary to the REC

cc R& D Office
Dr Christopher Nutting, Consultant Clinical Oncologist, Head of Head and Neck Unit RMH Chelsea

The Joint UCL/UCLH Ethics Committee
Committee Alpha
Research & Development
1st Floor, Vezey Strong Wing
112 Hampstead Road
London NW1 2LT
Tel: 020 7380 9579
Fax: 020 7380 9937
Website: www.uclh.org

Our Ref: PO/WW/03AL190

21 November 2003

Mr Laurence Newman
Consultant/Honorary Senior Lecturer
Maxillofacial Unit
UCLH
Mortimer Street

Dear Mr Newman

REC Ref No: **03/0263** *(please quote in all correspondence)*
REC Name: **Committee Alpha** *(please quote in all correspondence)*
Study Title: **Assessing the role of psychological factors in predicting subjective quality of life (QoL) in patients with head and neck cancer**

The Joint UCL/UCLH Committees on the Ethics for Human Research: Committee Alpha reviewed your application on 6 November 2003. The documents reviewed were as follows:

- REC application form
- Patient information sheet (version 1)
- Consent form
- Research protocol
- Questionnaire pack

The members of the committee present approved your application in principle, however, before final approval can be granted, the committee would like you to respond to the following concerns, which are detailed below:

- How would the information be kept anonymous, as all staff would be able to have sight of the answers?

- Page 2 of the patient information sheet under sub-heading *"Who is organising and funding the research?"* remove the word *"approved"* from the second line of the paragraph.

The Committee has delegated authority to the Chair and Vice-Chair to give you approval when it is felt a satisfactory response to the above issues has been received.

When submitting the response to the committee, please send revised documentation where appropriate highlighting the changes that you have made and give revised version numbers and dates.

Your application has been given a unique reference number please use it on all correspondence with the REC

Yours sincerely

p.p. **Mrs Patricia Orwell / Dr Steve Pereira**
Chair / Vice-Chair

Email: wendy.walker@uclh.org

Patron Her Majesty The Queen

THE ROYAL MARSDEN NHS TRUST

Research Ethics Committee

020 8661 3893

28th May 2004

Ms Carrie Llewellyn
Research Psychologist
Psychology Unit
5th Floor, Thomas Guy House
Guy's Hospital
LONDON SE1 9RT.

Dear Ms Llewellyn

RE: Protocol 2300 ***Assessing the role of psychosocial factors in predicting subjective quality of life (QoL) in patients with head and neck cancer***

Amendment date: 27/04/2004

The above amendment was reviewed by the Research Ethics Committee at the meeting held on 19th May 2004.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Protocol Amendment 3 (ver.1 27/04/2004)
Patient Information Sheet and Consent Form (Version 3 07/01/04)

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Management approval

Before implementing the amendment, you should check with the host organisation whether it affects their approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

Patron Her Majesty The Queen

THE ROYAL MARSDEN NHS TRUST

LONDON AND SURREY

REC reference number: 2300 **Please quote this number on all correspondence**

Yours sincerely

Christine Ferguson
Committee Administrator

Copy to: *Dr Chris Nutting, Head & Neck Unit, Royal Marsden*

Enclosures *List of names and professions of members who were present at the meeting and those who submitted written comments*

Downs Road SUTTON SM2 5PT Telephone: 020 8661 3893

APPENDIX XI: SATISFACTION WITH LIFE SCALE (SWLS)

APPENDIX XI: Satisfaction with Life Scale (SWLS)

This section is to find out how satisfied you are with your life at present.

Below are five statements that you may agree or disagree with.

Please tick the box that best applies and be open and honest in your responses.

	Strongly Disagree	Disagree	Slightly Disagree	Neither agree nor disagree	Slightly Agree	Agree	Strongly Agree
1. In most ways my life is close to my ideal.	☐	☐	☐	☐	☐	☐	☐
2. The conditions of my life are excellent.	☐	☐	☐	☐	☐	☐	☐
3. I am satisfied with my life.	☐	☐	☐	☐	☐	☐	☐
4. So far I have gained the important things I want in life.	☐	☐	☐	☐	☐	☐	☐
5. If I could live my life over, I would change almost nothing.	☐	☐	☐	☐	☐	☐	☐

APPENDIX XII: BRIEF IPQ (BIPQ)

TEXT BOUND INTO

THE SPINE

YOUR VIEWS ABOUT YOUR ILLNESS

We are interested in your views <u>now</u> about your illness and treatment.
Please circle the number on the scale that best indicates your response.

PQ1 How much does your illness still affect your life in general?

0 1 2 3 4 5 6 7 8 9 10

no affect at all — **severely affects my life**

PQ2 How long do you think your illness will continue?

0 1 2 3 4 5 6 7 8 9 10

a very short time — **forever**

PQ3 How much control do you feel you have over your illness?

0 1 2 3 4 5 6 7 8 9 10

absolutely no control — **extreme amount of control**

PQ4 How much do you think your treatment has helped your illness?

0 1 2 3 4 5 6 7 8 9 10

no effect at all — **extremely helpful**

PQ5 Are you still experiencing symptoms as a result of your illness?

Yes ❑ No ❑

PQ6 If yes, how severe are your symptoms?

0 1 2 3 4 5 6 7 8 9 10

not severe at all — **extremely severe**

PQ7 How concerned are you about your illness?

0 1 2 3 4 5 6 7 8 9 10

not at all concerned — **extremely concerned**

IPQ8 How well do you understand your illness now?

0 1 2 3 4 5 6 7 8 9 10

not at all **extremely well**

IPQ9 How much does your illness still affect you emotionally?
(e.g. does it make you angry, scared , upset or depressed)

0 1 2 3 4 5 6 7 8 9 10

not at all affected **extremely affected emotionally**

APPENDIX XIII: BELIEFS ABOUT MEDICINES QUESTIONNAIRE (BMQ) ITEMS USED FOR FOLLOW-UP STUDY

BELIEFS ABOUT TREATMENT

Please indicate how much you agree or disagree with the following statements about the treatment you received by ticking the appropriate box.

		Strongly Disagree	Disagree	Not sure	Agree	Strongly Agree
N4	Without the treatment I would be very ill	☐	☐	☐	☐	☐
N5	My treatment has protected me from becoming worse	☐	☐	☐	☐	☐
C2	I still sometimes worry about the long term effects of the treatment	☐	☐	☐	☐	☐
C4	My treatment has disrupted my life	☐	☐	☐	☐	☐

APPENDIX XIV: ITEMS ASSESSING EXPECTATIONS

EXPECTATIONS REGARDING YOUR TREATMENT AND RECOVERY

We would like to ask you about the kinds of expectations you may have had regarding your treatment and recovery. For each of the following questions please circle the response that best describes your answer.

EX1 To what degree have your expectations regarding the outcome of treatment been met? (I.e, cosmetic and/or physical effects of treatment)

better than expected	**about the same as expected**	**worse than expected**	**no expectations at all**

EX2 **At present,** to what degree have your expectations regarding the extent of recovery currently been met?

no expectations at all	**worse than expected**	**about the same as expected**	**better than expected**

EX3 To what extent have your expectations regarding the **whole treatment and recovery period to date** been fulfilled by your experiences?

not at all as I expected	**somewhat as I expected**	**mainly as I expected**	**completely as I expected**

APPENDIX XV: PRE-VALIDATION SATISFACTION WITH INFORMATION IN CANCER PROFILE (SCIP) SCORES

APPENDIX XV

Pre-treatment SCIP Scores – Satisfaction with amount & content of information

RELIABILITY ANALYSIS - SCALE (ALPHA)

		Mean	Std Dev	Cases
1.	T0_SI1B	.9020	.3003	51.0
2.	T0_SI2B	.9412	.2376	51.0
3.	T0_SI3B	.8824	.3254	51.0
4.	T0_SI4B	.8824	.3254	51.0
5.	T0_SI5B	.7843	.4154	51.0
6.	T0_SI6B	.7647	.4284	51.0
7.	T0_SI7B	.6078	.4931	51.0
8.	T0_SI8B	.5686	.5002	51.0
9.	T0_SI9B	.7059	.4602	51.0
10.	T0_SI10B	.8039	.4010	51.0
11.	T0_SI11B	.8039	.4010	51.0
12.	T0_SI12B	.6078	.4931	51.0
13.	T0_SI13B	.7843	.4154	51.0
14.	T0_SI14B	.8431	.3673	51.0
15.	T0_SI15B	.7843	.4154	51.0
16.	T0_SI16B	.6667	.4761	51.0
17.	T0_SI17B	.6275	.4883	51.0
18.	T0_SI18B	.6863	.4686	51.0

RELIABILITY ANALYSIS - SCALE (ALPHA)

N of Cases = 51.0

Statistics for	Mean	Variance	Std Dev	N of Variables
Scale	13.6471	19.3129	4.3946	18

Item-total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Alpha if Item Deleted
T0_SI1B	12.7451	18.6337	.2272	.	.8881
T0_SI2B	12.7059	18.6518	.2946	.	.8863
T0_SI3B	12.7647	18.5035	.2513	.	.8878
T0_SI4B	12.7647	17.8235	.5036	.	.8811
T0_SI5B	12.8627	17.0008	.6246	.	.8765
T0_SI6B	12.8824	16.5859	.7289	.	.8725
T0_SI7B	13.0392	16.5184	.6366	.	.8756
T0_SI8B	13.0784	16.5937	.6059	.	.8769
T0_SI9B	12.9412	17.4165	.4386	.	.8833
T0_SI10B	12.8431	17.0149	.6461	.	.8759
T0_SI11B	12.8431	17.2949	.5569	.	.8789
T0_SI12B	13.0392	17.5184	.3758	.	.8863
T0_SI13B	12.8627	16.9608	.6370	.	.8760
T0_SI14B	12.8039	17.4808	.5526	.	.8793
T0_SI15B	12.8627	17.7208	.4059	.	.8840
T0_SI16B	12.9804	17.0196	.5261	.	.8801
T0_SI17B	13.0196	16.6596	.6058	.	.8769
T0_SI18B	12.9608	16.7584	.6086	.	.8768

Reliability Coefficients 18 items

Alpha = .8862 Standardized item alpha = .8838

Pre-treatment SCIP Scores – Satisfaction with form and timing of information

RELIABILITY ANALYSIS - SCALE (ALPHA)

		Mean	Std Dev	Cases
1.	SIHNC19	4.1429	.6206	70.0
2.	SIHNC20	4.0143	.7121	70.0
3.	SIHNC21	3.6714	1.0032	70.0
4.	SIHNC22	4.2143	.6570	70.0
5.	SIHNC23	3.9571	.7882	70.0
6.	SIHNC24	4.0571	.6786	70.0
7.	SIHNC25	4.1714	.4495	70.0

N of Cases = 70.0

Statistics for	Mean	Variance	Std Dev	N of Variables
Scale	28.2286	14.0919	3.7539	7

RELIABILITY ANALYSIS - SCALE (ALPHA)

Item-total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Alpha if Item Deleted
SIHNC19	24.0857	10.6882	.7440	.6865	.8375
SIHNC20	24.2143	10.4317	.6855	.6069	.8426
SIHNC21	24.5571	9.8155	.5202	.3398	.8812
SIHNC22	24.0143	10.4491	.7560	.5929	.8345
SIHNC23	24.2714	10.2876	.6295	.4128	.8509
SIHNC24	24.1714	10.5789	.6916	.5041	.8423
SIHNC25	24.0571	11.8228	.6687	.5522	.8537

Reliability Coefficients 7 items

Alpha = .8675 Standardized item alpha = .8872

APPENDIX XVI: ITEMS INCLUDED IN FINAL SCIP QUESTIONNAIRE

Items included in the Satisfaction with Cancer Information Profile (SCIP)*

Subscale	Do you feel as if you have received enough information about:	Too Much	About Right	Too Little	None Wanted
Satisfaction with the amount and content of information	Whether the treatment has any unwanted side-effects What the risks of you experiencing side effects are What the risks of you experiencing complications are What you should do if you experience unwanted side-effects Whether your treatment interferes with other medicines you may be taking How you may expect to feel immediately after treatment The effects of treatment on your ability to work Who to ask/where to go for possible financial support Whether you may need further treatment in the future The effect of treatment on your appearance The long term impact of treatment on functioning (daily activities) How long you expect recovery to take How your treatment may impact on your quality of life over the next year Patient support groups for you and your partner	Score: 0	1	0	1 **Possible subscale score: 0-14**

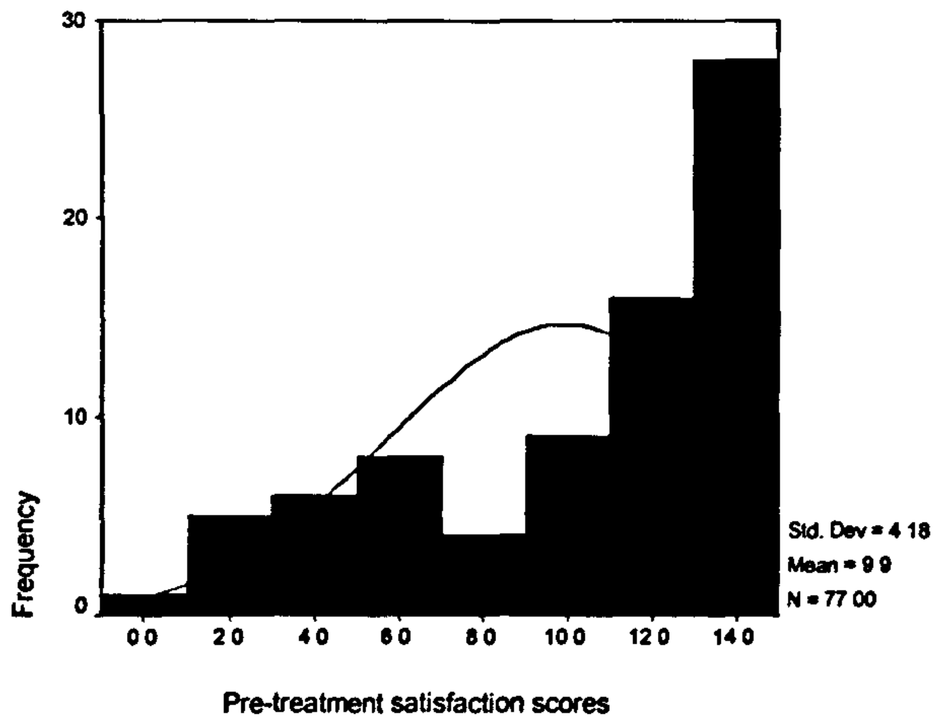
Subscale	Overall, how would you rate the following:	very satisfied,	satisfied	neither	dissatisfied	very dissatisfied
Satisfaction with the form and timing of information	The usefulness of the information to you The usefulness of the information to your partner/family The amount of written information supplied The amount of verbal information supplied The timing at which you received information The detail of the information given to you How understandable the information was to you	Score: 5	4	3	2	1 **Possible subscale score: 7-35**

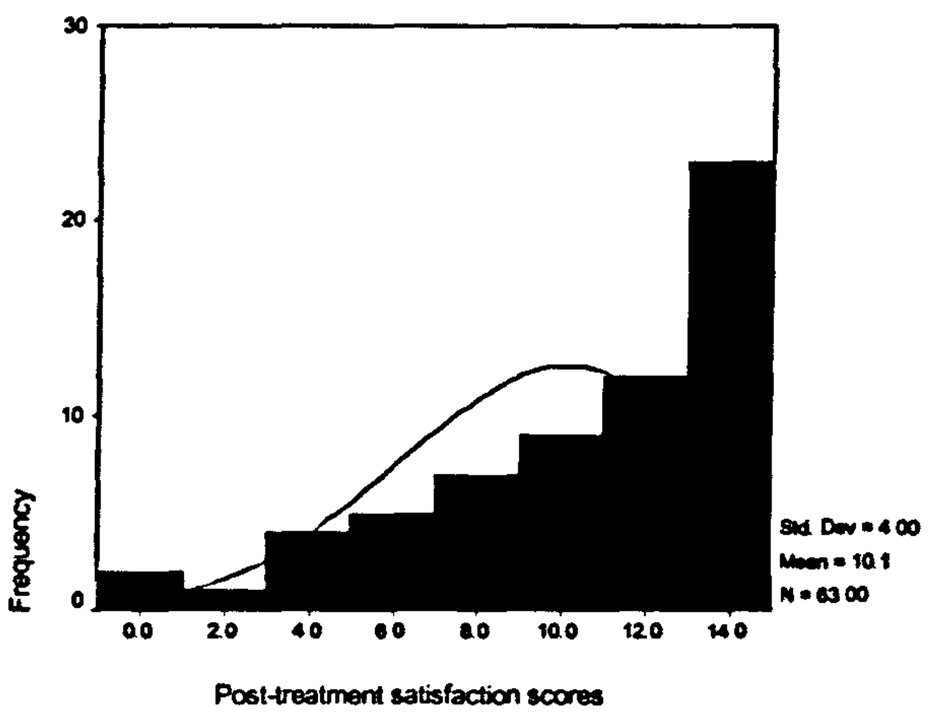
* Actual questionnaire is formatted differently. This gives a representation of the items, sections and scoring for information only.

APPENDIX XVII: HISTOGRAMS OF SCIP SUBSCALE SCORES

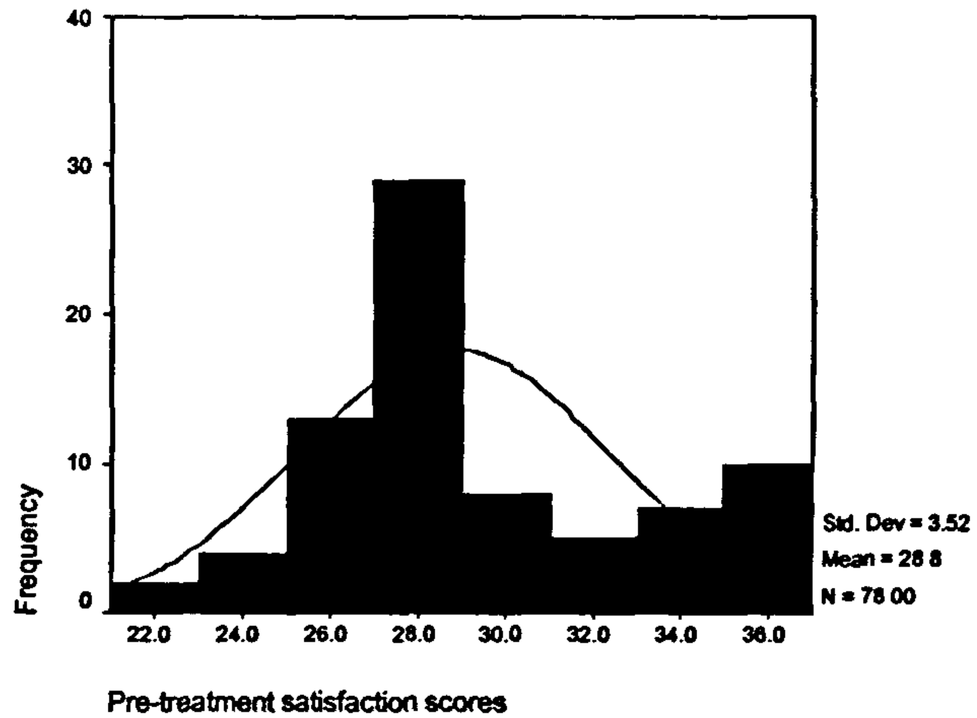
Histograms showing the distribution of pre- and post treatment patient scores for the two subscales of the SCIP.

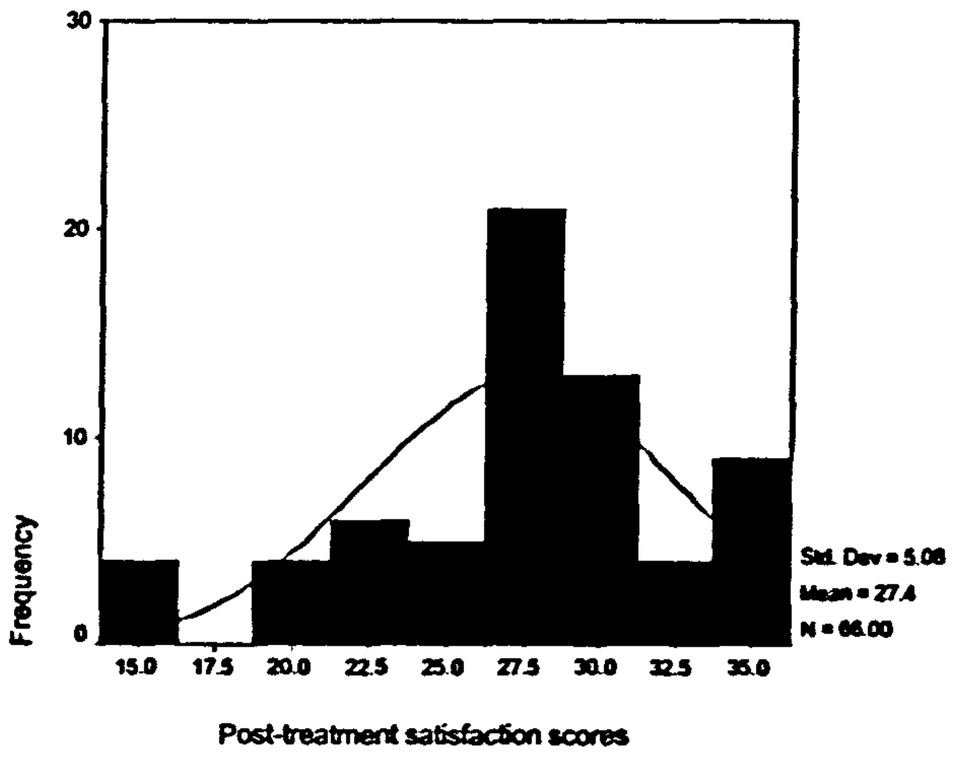
Satisfaction with content & amount of information





Satisfaction with form & timing of information





PUBLICATION LIST

I) Llewellyn CD, McGurk M, Weinman J. (2005) Striking the right balance: a qualitative pilot study examining the role of information on the development of expectations in patients with head and neck cancer. *Psychology, Health & Medicine*, 10:2;180-193.

II) Llewellyn CD, McGurk M, Weinman J. (2005) Are psycho-social and behavioural factors related to Health Related- Quality of Life in patients with head and neck cancer? A systematic review. *Oral Oncology;* 41:440-454.

III) Llewellyn CD, McGurk M, Weinman J. (2005) Head and Neck Cancer: To what extent can psychological factors explain differences between health related quality of life (HR-QoL) and individualised QoL? *British Journal of Oral & Maxillofacial Surgery*, in press.

Psychology, Health & Medicine,
May 2005; 10(2): 180–193

Routledge
Taylor & Francis Group

Striking the right balance: A qualitative pilot study examining the role of information on the development of expectations in patients treated for head and neck cancer

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Abstract

The a priori aims of this study were, firstly, to investigate the types of expectations patients treated for head and neck cancer had prior to treatment and the extent to which these had been met post-treatment. Secondly, to investigate the role information played on the development of expectations. Semi-structured interviews were conducted with 15 patients. Data were analysed and classified using a Framework Analysis Approach. Expectations were subcategorized as either 'Specific' or 'Global'. 'Specific' expectations centred around: side effects of treatment; post-treatment aesthetics and the recovery process. 'Global' expectations centred around the whole cancer experience. A large proportion of patients described the whole experience as being much worse than they had anticipated. 'The role of information on expectations' was subcategorized into: 'too much' information, 'too little' information and the 'timing' of information. In conclusion, there were large variations in the types of expectations patients had, and between patients expectations and their actual experiences. Expectations appeared to be influenced by the information received and retained. Respondents emphasized the fine line between being given 'too much' information at the wrong time and 'not enough' information at the right time. This study has clear implications for reducing pre- and post-treatment uncertainty by supplying verbal and written information on a timely and individual basis, in order to reduce the mismatch between patient expectations and experiences.

Keywords: *Qualitative, head and neck, cancer, information, expectations*

Introduction

The incidence of cancer of the mouth and pharynx ranks *sixth* in the world and ranks *third* in developing countries (Parkin et al., 1999). Striking differences in incidence rates exist between different geographical (and therefore cultural, ethnic and socio-economic) regions. Cancer of the mouth and throat (ICD-10: C00-C14 & C32), is the fifth most common anatomical site for cancer in the world, with half a million incident cases of oral, pharyngeal and laryngeal cancer in 1990 (Ferlay et al., 1998; Parkin et al., 1999). Altogether, the figures for head and neck cancer (HNC) represent a substantial disease burden, with high mortality rates of 54% overall: death to registration ratios range from 0.47 to 0.65 according to site (Johnson, 2002).

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ISSN 1354-8506 print/ISSN 1465-3966 online
DOI: 10.1080/1354850042000326593

Treating HNC patients for cure involves either surgery, radiotherapy and/or chemotherapy in varying combinations. Each treatment has its own toxicities and adverse late effects, which are often intensified when used in combination. Small primary tumours can be eradicated by either surgery or radiotherapy. In cases involving less accessible lesions (e.g. the vocal cords, tonsil and hypopharynx), radical radiotherapy can enable good function and cosmesis to be retained and this is generally the treatment of choice. Salvage surgery may be required in those patients with residual or recurrent disease after radiotherapy (Bloom, 1987).

The high doses of radiotherapy required to gain loco-regional control of HNC are associated with an increased risk to normal tissue with significant impacts on quality of life (Hammerlid et al., 1997). Acute skin and mucosal reactions are common during irradiation and generally subside after treatment. Late irradiation-induced changes can lead to fibrosis and may lead to permanent and serious problems with regard to function, comfort and cosmesis. The most frequent effects following treatment with radiotherapy are due to the reduction of saliva following direct or incidental irradiation of the salivary glands. The resulting mouth dryness (Xerostomia) may lead to rapid and severe widespread dental caries (Bloom, 1987), difficulties eating with a decreased or lack of taste and smell, or problems speaking.

During the last 20 years, advances in intra-oral soft tissue reconstruction by revascularized tissue transfer (e.g. from pectoral or forearm donor sites) have lead to more extensive tumour ablation in patients, as even large defects can be repaired in one step procedures. However, the size of the tumour and reconstruction technique will have an effect on the short- and long-term function of the organ, frequently leading to problems eating, drinking, speaking or even breathing. Even minor surgery can lead to significant facial disfigurement. The traditional gold standard for regional disease control has been radical resection of all lymph bearing tissues in the neck. Despite modifications to the 'classic' dissection, neck dissection is still responsible for permanent and significant change in shoulder function as well as increased postoperative pain. Although curative or palliative in intent, all the procedures outlined above have their own associated morbidities and consequences which the patient should be informed of.

Cancer of the head and neck not only poses a threat to life but, in patients who survive, consequences of the disease and treatment can be far-reaching and especially traumatic if unanticipated. These unexpected consequences may, in turn, lead to long-term difficulties with adjustment. Evidence from the literature has shown that pre-treatment expectations influence recovery from surgery (McCarthy et al., 2003) and health related quality of life (HR-QoL) after radiotherapy (Koller et al., 2000) and HR-QoL during in-patient stays (Staniszewska, 1999) in a wide range of illness groups.

Although unforeseen complications can arise, some of the uncertainty and trauma could be lessened with accurate and timely information at a level that patients can understand. For example, Leydon et al. (2000) demonstrated that not all patients want extensive information about their condition and treatment at all stages of their illness. However, patients undergoing surgery often experience considerable anxiety as a result of receiving too little information or information that they cannot understand (Krupat et al., 2000). Studies have shown that the majority of written pre-operative instructions are not understood by patients (Livingston, 1989) and in another study, that only 60% of cancer patients could correctly describe their treatment (Cassileth et al., 1980).

In addition to the timing and format of the information supplied, another key issue is the mechanism by which information benefits the patient. Janis (1958) argued that pre-operative information allows patients to engage in 'work of worrying'. He proposed that information is

useful because it allows patients to anticipate and rehearse the stressful events they are about to encounter and therefore cope more successfully with them. However, it has also been recognized that the benefits of information may vary considerably according to the timing of the information (Pinder, 1990) and the personality and demographics of the patient (Mahler & Kulik, 1991; Miller & Mangan, 1983).

Despite the growing volume of research into the informational needs of patients with cancer in general, little is known specifically about the informational requirements of patients with highly traumatic diseases such as HNC. It is also not known whether the information received by patients plays a role in the development of expectations.

Therefore, this study sought to examine in depth:

(1) The types of expectations patients had prior to treatment and the extent to which patients considered that these expectations had been met post treatment.
(2) The role of information on the development of expectations.

Method

Recruitment of participants

Patients were recruited from head and neck cancer clinics run at two London Hospital NHS Trusts and were based on a convenience sample. This was to minimize any bias that may have been created by pre-selecting patients into the study. Patients may have been more likely to talk about their experiences in the context of a clinical review visit than returning on a separate occasion. Recruitment criteria were any post-treatment patient up to 18 months post-diagnosis and free of disease. This 18 months post-diagnosis cut off point was for several reasons. Most importantly to ensure that experiences were relatively recent to avoid problems with recall, secondly, to explore a spectrum of opinions at different stages of treatment and recovery and, thirdly, for more practical reasons of increasing the sample eligible for recruitment. Patients were recruited during the period from 10th January 2003 to 5th March 2003. Ethical approval for this study was granted by the local research ethics committee and consent was obtained from all participants.

Data collection

Semi-structured interviews were conducted in quiet rooms in the clinics. The interviews were iterative from the beginning, meaning that the first interview schedule was transformed over the first few interviews according to the usefulness and responsiveness to certain questions. Interviews typically began with a short discussion about why they were in the clinic on that day and how long it had been since they had first been diagnosed, in order to establish rapport. A broad opening question such as; 'could you describe for me some of the experiences you have gone through since your diagnosis?' then followed and participants were prompted to think back over their experiences and expectations if required. Questions were presented in as neutral a way as possible to minimize potential bias. The interviewer encouraged the participant to elaborate on stories and situations to illustrate important points. All interviews were tape-recorded and lasted between approximately 15 to 55 minutes, the average being about thirty minutes in duration. Transcripts were produced shortly after each interview. Demographic and medical data were collected from hospital medical records.

Data analysis

Data were analysed using a Framework Analysis Approach (Ritchie & Spencer, 1994). This is a matrix-based approach to qualitative data analysis, which, is based on transcripts produced verbatim from the taped interviews. This technique involves identifying recurring and important themes based on a combination of a priori issues, emergent themes and recurring attitudes or experiences. Major themes in the data arising in these transcripts (determined by an initial read through of all the transcripts and then in-depth analyses of the first seven transcripts) were then used as headings/themes under which the systematic charting of the content of all the transcripts was carried out. This ensured that the themes could be refined. Any new themes that subsequently arose were added to the framework. This method ensured that the diversity of the participants' experiences were encapsulated. Analysis was carried out after all the participants had been interviewed and this was to minimize the potential bias of one interview influencing the next based on any framework that subsequently emerged.

Reliability of the data

In order to comment on the reliability of the data, a second rater (CK) was given the framework of emergent themes/headings and the verbatim transcripts and asked to appraise them according to their content. Any discrepancies that arose were discussed until inter-rater satisfaction was achieved.

Results

Profile of participants

Participants were 15 patients treated for head and neck cancer and under the care of two maxillo-facial/oral surgery consultants, attending clinics at two south London hospitals. One male patient refused to take part and one taped interview (also a male patient) had to be discarded due to extraneous background noise. This gave a response rate of 88%.

Table I provides a breakdown of the demographic and treatment profiles of the participants. Ten participants (67%) were female. Ages ranged from 38 to 75 (mean = 54; median = 51; SD = 10.5). All patients except 2 classified themselves as white UK ethnic origin, one patient was Asian and one patient was Iranian. The time since diagnosis ranged from $1\frac{1}{2}$ to 18 months (median = 9; mean = 9.7; SD = 4.8). All tumours except one (adenocarcinoma) were squamous cell carcinomas (SCC). Three patients had carcinoma of the tongue, three of the mandible, four of the maxillary region, three floor of mouth and one each of the tonsil and palate. All patients except one had surgical treatment and the majority also had radiation therapy. All patients were free of disease at the time of interview. Figures after quotes refer to the interview no., sex and age of the participant.

Two main themes of 'patient expectations' and 'the role of information' were explored and which resulted in a number of sub-themes (Table II). The results have been presented in two parts, according to each main theme.

Part 1. Patient expectations

Respondents described expectations reflecting two central themes: 'Global' expectations regarding the whole cancer experience and more '*specific*' expectations, centred around side effects, aesthetic aspects and the recovery process.

Table I. Characteristics of participants.

Pt. no.	Current age (yrs)	Sex	Approx. time since diagnosis in months	Approx. time since end of treatment in months	Site of cancer	TNM‡ stage	Type of operation	Total treatment modality*
1	47	F	12	9	Maxillary/gum	T stage unknown N0M0	Hemi-maxillectomy	S, RT, ND
2	42	F	15½	15	Maxillary	T2N0M0	Hemi-manibulectomy, maxillectomy	S, ND
3	56	M	18	15	Mandible/ floor of mouth	T4N2M0	Mandibulectomy + free-flap	S, ND
4	51	M	5	2	Tongue	T3N0M0	Glossectomy	S, RT, ND
5	49	M	7½	2	Maxillary	T4N0M0	Maxillectomy + free-flap	S, RT, ND
6	55	M	1½	1 (pre-RT)	Mandible	T4N1M0	Mandibulectomy + free-flap	S, ND pre-RT
7	61	F	12	11	Maxillary	T4N0M0	Hemi-maxillectomy + free-flap	S
8	75	M	10	6	Tongue/floor of mouth	T2N1M0	Glossectomy + free-flap	S, IRT, ND
9	70	F	12½	11	Palate	Low grade Adenocarcinoma	Local excision	S
10	48	F	4½	1½	Tonsil	T1N0M0	-	RT, CT
11†	63	F	Not known	9	Mandible	T4N0M0	Hemi-mandibulectomy + free-flap	S, RT, ND
12	59	F	12½	12	Tongue	T1N0M0	Partial glossectomy	S, ND
13	47	F	3½	3	Floor of mouth	T2N0M0	Partial glossectomy + free-flap	S, ND
14	38	F	9	7	Floor of mouth	T3N1M0	Partial glossectomy + free-flap	S, IRT
15†	43	F	15	10	Cheek/ floor of mouth	T4N0M0	Mandibulectomy + free-flap	S, RT, ND

Note: † = 2 patients contracted post-surgical Methicillin-Resistant Staphylococcus Aureus (MRSA)
‡ = TNM staging of tumour (American Joint Committee on Cancer, 1988)
* S = Surgery; RT = radiotherapy; IRT = Irradium wire implant therapy; CT = chemotherapy; ND = Neck dissection

Table II. Structure of main themes, sub-themes and examples of issues to emerge from interviews.

Main Theme	Sub-theme	Example of issues to emerge
1. Patient expectations:	Global	Unexpected enormity of treatment / recovery
		Expectations being surpassed by reality
	Specific	Side-effects of treatment
		Aesthetical outcome
		Recovery as a process
2. Information influencing expectations through:	Too much information	Limits to how much info can be 'taken in'
		Repercussions on ability to cope
	Too little information	'Missing' information
		Lack of clarity
	Timing of information	Knowledge gap
		Uncertainty

Global expectations

A large proportion of respondents described the whole experience as being worse than they had imagined. A few patients expressed a sense of unexpected 'enormity' about the surgical treatment and the subsequent physical recovery process, particularly those who had also received radiotherapy, as emphasized by:

> 'I didn't realize how big it was all going to be...Even had I been told, I don't think I would have expected what happened'. [2,F,42]

> '...he (the surgeon) tells me it's not dangerous – it's not a big operation. But when I come here I was surprised – it was a big operation'. [4,M,51]

> 'I'll be quite honest, I didn't realize the operation at the time would pull me down as regards health so much. I think because I lost so much weight, I felt so weak. It affected me more than I thought it was going to at the time.' [9,F,70]

Similarly, patients reported feeling surprise (post-treatment) at the extent of the operation due to the relatively small part of the lesion visible to the patient. The fact the tumour was extensive but not visible had obviously not been explained to the patient:

> 'I wasn't expecting such a large area (affected) from what seemed such a small, well, not a small operation, but such a large affected area from a small area that was involved in the surgery'. [12,F,59]

A few respondents reported that the whole cancer experience had been better than they had been expecting. One woman described how she felt physically better now than she had thought she would:

> 'Well, I did think that I may feel worse actually. Everybody says you'll feel tired and you won't be able to do this or won't be able to do that but I'm doing everything so...' [10,F,48]

Similarly, another woman reflected on her ability to cope, despite not having any concrete expectations:

'I think I've actually done better than what I thought I might. Because you don't know. You just don't really know, well, I didn't know what to expect. Perhaps I didn't ask enough questions but then I didn't want to know... I think I've coped a lot better than I thought I would'. [1,F,47]

Specific expectations

Side effects. Expectations regarding specific outcomes of treatment and recovery reflected both positive and negative aspects. Respondents were able to describe their experiences of specific side effects that had exceeded their expectations, for example,

'There was a lot less pain than I expected. I was able to eat quite quickly and I was able to talk better than I thought I would'. [12,F,59]

'I was also told that they didn't think that I would speak for six months, but I did. As soon as they took me off tracheostomy, they could understand me basically, so that was a bonus'. [14,F,38]

Conversely, a few respondents recalled their surprise at experiencing arm and shoulder mobility problems (due to the neck dissection):

'I had mobility problems for quite some time which I hadn't expected. I couldn't raise my left arm very much... I wasn't expecting as much numbness...' [12,F,59]

One patient, at a relatively early stage since diagnosis (5 months) described his current situation after undergoing radiotherapy:

'It's all a lot worse than I thought it would be. I can't eat because I have no saliva both sides, it's very dry'. [4,M,51]

Aesthetics. Aside from functional aspects, disfigurement immediately after the operation was a particularly emotive issue due to the uncertainty surrounding the extent of surgery. Many respondents chose not to look at themselves immediately afterwards due to the large amount of swelling, however, one woman's expectations were surpassed when she finally looked at herself a week later:

'I actually looked a hell of a lot better than I thought I would... 'cos I thought I might lose a cheek or outer skin whereas all mine is internal'. [1,F,47]

Respondents tentatively expressed expectations and hopes regarding future aesthetic improvement, either for further cosmetic procedures or healing with time.

The recovery process. Expectations regarding the recovery process seemed realistic in some people who recognized that recovery would take place over an extended period of time and would be challenging. For some people, pre-treatment expectations had been less realistic in hindsight, with expectations that after a couple of months they would be feeling the same or better than they had at diagnosis. For example, expectations regarding current health status, were mentioned by a couple of respondents. One woman struggled to conceal her disappointment at not recovering as quickly as she was expecting and

attempted to put it in perspective by suggesting her expectations may have been unrealistically optimistic:

> 'I had expected it to be a little better. Maybe I was just being overly optimistic, you know (pause) but I don't expect (pause) I mean, the important thing is that the cancer is gone but I had some major setbacks on the ward'. [15,F,43]

Additionally, one woman described how she was expecting physical changes but was uncertain how they would manifest. She also recalled not expecting any psychological problems. However, she was currently experiencing panic attacks related to her loss of confidence and altered appearance:

> 'Well, I did expect that there might be some big changes, perhaps physically. I didn't expect any psychological problems but I did expect to be physically different and I wasn't sure what that would mean'. [12,F,59].

Expectations regarding recovery were also revealed through expectations of returning to work. Expectations appeared to be related to prior advice from the consultant and comparison with other patients who had undergone similar procedures. These proved to be exceeded in some. For example:

> 'Mr X said it would be minimum 6–7 months up to a year, 2 years depending on individuals. I was actually back at work in November, the November after the April (7 months)'. [1,F,47]

Prior expectations had not been met in others:

> 'It had been my expectation to go back to work at the end of this month, having finished the radiotherapy at the end of October. I thought 4–5 weeks recovery, back to work. But no'. [5,M,49]

Patients' expectations were reported to change over time. Many post-treatment patients confided how shocked they were at the extent to which life in general had actually changed afterwards, despite expecting some alteration. A few respondents mentioned that their expectations changed throughout the recovery and the post-treatment period, lowering with experience of complications or problems. One respondent reported that she had learnt to be more patient regarding the speed of recovery after her expectations had not been met. This appeared to suggest that many people were optimistic in the early stages of the recovery process, but, with time and experience, people later developed more realistic expectations, suggestive of adaptive processes taking place.

Part 2. The role of information on the development of expectations

Many respondents presented a conflicting picture of needs and requirements, between not wanting too much information on the possible complications and side effects associated with treatment but feeling in hindsight that they were 'missing' information regarding specific events. Explanations for this variation were forwarded by respondents, mainly relating to pre-treatment fear and perceived ability to cope with too much knowledge.

Too much information

Many respondents reflected that they hadn't wanted 'too much' information pre-operatively. This appeared to be related to fear and a perceived lack of ability to cope. This was illustrated by statements such as:

> 'I only needed to know what was needed to be known. Because if I'd had too much information you would have found me in the corner with a vodka bottle'. [1,F,47]

and;

> 'there's a limit to how much one can take in actually on something like this and how much you can actually cope with. Sometimes if you knew, like, any challenging thing you have to go through - if you knew all the horrible things that were going to happen you'd be like, 'no way! Thanks a lot'. [13,F,47]

Too little information

Although the general level of satisfaction with information was reported to be high, a few respondents reflected that there had been a distinct lack of information on the long-term impact on life and information on financial benefits available. For many respondents who reported 'missing' information pre-treatment, psychological consequences (such as anxiety and depression) were revealed post-treatment. A few respondents reported unexpected long-term side effects which they related to 'missing information'.

For example:

> 'One thing I was very shocked by was that I couldn't speak after the operation . . . It took a couple of weeks until I was sure I was going to be able to talk. The other thing I was very numb . . . No, I hadn't known about that. So it was quite missing information. I was quite shocked by that because I really had been expecting that the numbness would be temporary'. [13,F,47]

Expectations were clearly related to the information given by the treating staff and the risks associated with the particular treatment recommended. Many respondents reported some aspect of treatment or recovery that they were not told of (or couldn't recall being told). There was a common lack of clarity regarding the effects of radiotherapy, from hardening of the scar tissue from surgery or developing bald patches on the head, to major complications of failure of facial skin grafts. Many respondents reported a lack of understanding regarding how the effects of radiotherapy would make them feel 'setback' after recovery from surgery.

The variance between what to expect derived from detailed information and the actual experience was dramatically highlighted by one respondent:

> 'Nearly all that's happened, the doctors told me beforehand. I was given a massive amount of literature, booklets which I studiously read, so I could almost foretell what was going to happen. The only thing that has changed, that was quite significant, was that after the radiotherapy (pause) I didn't expect the radiotherapy to burn holes in my face'. [5,M,49]

A few of the patients contracted post-surgical Methicillin-Resistant Staphylococcus Aureus (MRSA) and felt particularly anxious and uninformed. This was emphasized by one woman who described her distress at the lack of information:

> 'It was a nightmare in that nobody could tell you it, would tell you anything. And everybody was embarrassed about it...Somebody had forgotten to tell the anaesthetist that I had MRSA and there was all this kerffufle whilst they sorted that out'. [11,F,63]

Timing of information

The lack of specific information or 'missing' information appeared to be related to the timing of information. Previous quotes have demonstrated that not all patients wanted detailed information at all stages of the illness, however, one respondent suggested that patients should have full knowledge of all possible side effects and outcomes of treatment, prior to treatment, regardless of the anxiety this may provoke. The same respondent later mentioned that not knowing the full facts when complications arose was a major source of anxiety for him:

> '...the times when things were going wrong and nobody was telling me were the times that I became anxious, agitated and concerned...' [5,M,49]

This was further emphasized by a couple of respondents who considered that the lack of information or clarity stemmed from a 'knowledge gap' 'between a full understanding of what's going to happen to you and what information can convey'. [12,F,59] . This was perceived to be caused by two factors, namely, the lack of time between diagnosis and treatment and the fact that traumatic experiences are indescribable until they've been experienced (likened to childbirth by a couple of women). The shock of diagnosis and the lack of time to assimilate the information were highlighted thus;

> 'At that time, when they've just told you, you have cancer and you're just about to have major surgery, you're not really listening...your mind's not on it'. [3,M,56]

and;

> 'It was all carefully explained but it doesn't really register in the short time you have to think about it. You're trying to cope with a lot of information and you're not feeling very well'. [12,F,59]

Discussion

The findings from this qualitative study give increased insight into how pre- and post-treatment expectations in a sample of head and neck cancer patients are derived in part from information received. Respondents described expectations reflecting two sub-themes: relating to 'specific' expectations centred around side effects; aesthetic aspects of treatment and the recovery process; and 'global' expectations regarding the whole cancer experience. Favourable experiences were underpinned by expectations being surpassed.

This pilot study also highlighted the individual nature of the information giving process, whereby many patients did not want too much detailed information about their illness and treatment, especially at the early stages between diagnosis and treatment, yet many

respondents required a detailed breakdown of all the possible complications and variables associated with the recovery process. These differences in requirements may have been due to differences in personality and/or coping strategies between patients. Research has indicated that stable individual differences exist between patients' tendencies either to seek or to avoid potentially stressful information about cancer and other threatening medical procedures. Miller (1992, 1997) proposed that people react to health threats by coping in one of two ways. Either by trying to avoid or minimize obtaining stressful information and by distracting themselves from threatening information (*blunting* coping style) or by attending and scanning for threat relevant information about aversive medical events and rehearsing and amplifying them cognitively (*monitoring* coping style) (Miller, 1992 and 1997). Tentative support for these coping styles was evidenced in the present study whereby some patients explicitly stated that they hadn't wanted to know pre-operatively what was going to happen to them in detail versus some respondents who had sought out detailed information. The data from the interviews also indicated that there was probably a dynamic relationship between a patient's need for information, expectations and coping. Modifying this cycle by intervention either at the informational level or through targeting specific coping strategies may influence patients expectations.

The role of information has previously been investigated in relation to a range of outcomes after treatment for head and neck cancer. Perceptions of adequate information from specialists were found to be predictors of positive rehabilitation outcomes in laryngectomy patients treated 2–6 years previously (De Boer et al., 1995). Similarly, satisfaction with information provided shortly before the end of radiotherapy was found to be a significant predictor of quality of life (QoL) in nasopharyngeal cancer patients 4 months later (Yu et al., 2001). The relationship between information and QoL has not been found to be straightforward. Kreitler et al. (1995) concluded from a study of 55 head and neck cancer patients that 'the psychosocial effects of the information the patient has at his or her disposal about the disease and its prognosis are greater than the effects of the severity of disease per se'. This suggests that the psycho-social effects of the disease and treatment are not necessarily direct functions of disease severity but are mediated by the meanings the patient assigns to the disease and the total situation. Information is a major determinant of the meanings assigned along with the cognitive representation of a health threat. However, Kreitler et al. (1995) found that the effects of providing information were in some respects beneficial and in others detrimental from a psychological point of view (Kreitler et al., 1995). Our study also found that for some people, too much information meant that they were unable to cope with the health threat due to high feelings of anxiety and fear. Although we did not seek to investigate the role of information on subsequent QoL or mood in our study, the evidence suggests that pre-treatment information is relevant to post-treatment adaptational processes/rehabilitation and these could be mediated by the individual's expectations. Indeed, as Calman proposed in 1984, QoL should be considered 'the extent to which our hopes and ambitions are matched by experience'. He argued that to improve QoL, health care should 'narrow the gap between a patient's hopes and expectations and what actually happens' (Calman, 1984). Through tailoring information to the individual, the mismatch between unrealistic expectations and experience could be narrowed thus potentially improving outcome.

This study highlighted that patients' needs were frequently not being met. This is consistent with a report by The National Cancer Alliance (2002), who highlighted through discussions with a focus group that although some patients had received written information, this was inadequate for their needs. A study by Edwards (1998), also highlighted the lack of satisfaction regarding information giving. It was suggested that

patients wanted to have more information about the impact of their treatment and about different treatment options rather than details of the operation. In addition, Mesters et al. (2001) found that more supportive information about access to help and solutions was required.

Many extraneous factors contribute to the information giving process (such as: the time available to the patient, the presence of a multidisciplinary team, patient factors...etc.). However, the majority of patients would like to be provided with written information and explanations about their treatment, advice on how to manage the effects of the treatment on their daily lives and adequate preparation prior to discharge from hospital. Written information is especially pertinent in cases where the patient is being subjected to 'too much information' around the time of diagnosis. It may even be feasible to provide the patient with a tape recording of early consultations to listen to at a time appropriate to them. Information about the late onset of symptoms (particularly with radiotherapy) should be provided on a written basis as contact with the relevant health care professional may not be feasible after treatment has ended.

Evidence, involving patients with other illnesses, suggests that pre-treatment expectations can have an influence on post-treatment outcomes in both a negative and positive way. For example, Iversen et al. (1998) found that patients having surgery for lumbar spinal stenosis who had ambitious pre-surgery expectations for physical functioning were more likely to have improved function and satisfaction 6 months later. Conversely, having unmet expectations regarding outcome (e.g. high expectations regarding pain relief) resulted in worse perceptions of outcome, such as more pain and less satisfaction with pain relief post-surgery. This highlights the importance of patients to have an optimistic stance regarding outcomes but without expectations being unduly unrealistic.

Regarding the potential limitations, the data gained from the present study may be biased towards patients who have coped relatively well since diagnosis and who return for review visits. The majority of the patients had speech impediments to various degrees. This provided difficulties with transcribing, however, with careful listening and transcribing the interviews shortly afterward conducting them, this was not a problem, excluding one male case which combined with extraneous background noise, had to be discarded. The sample of patients interviewed were not representative of a typical sex ratio expected with HNC and this has to be acknowledged as a limitation of using a convenience sample. Although the nature of qualitative research is not to provide generalizable data, and the aim of the study was to explore patient expectations regarding recovery and outcome, in an area such as HNC where there are clear gender implications of having a disease that impacts aesthetically, a more representative sample may have provided different results.

The patients interviewed were at different periods of recovery, which may have had implications for memory biases. Patients were generally more upset when in the first stages of adjustment and patients having a longer period of recovery may have forgotten the pre-treatment expectations they had.

More pertinent to qualitative research is the issue of introducing biases into the data. This can occur at the time of the interviewer due to the person interviewing, whilst interpreting the data or even due to variables such as the time of interview, the interview room and interruptions by other staff. A more linear approach to data analysis was adopted in terms of analysing the data after all the interviews had been conducted which could be considered a limitation of the study. However, the intention was to elicit the patient's perspective before forming a framework and therefore any potential biases and assumptions, before all the interviews had been conducted.

In conclusion, this pilot study produced a rich amount of material about the types of expectations individuals with HNC had at various stages of their treatment and recovery. Large variations between patient expectations and the actual experiences that were described were revealed. Expectations, both global and specific, seemed to be derived in part from the information received. Satisfying patients' needs for information has important implications for patient outcome. Reducing the uncertainty pre-treatment and narrowing the gap between expectation and actual experience may reduce feelings of depression and anxiety, as a result of experiencing unexpected negative events. This could easily be achieved by providing more written information on topics of importance to patients on a timely basis. Further research would be needed to explore the relationship between the fulfilment of pre-treatment patient expectations and patient outcomes, such as QoL or depressive symptoms, post-treatment.

Acknowledgements

Christine Karamanidou for providing a secondary rating of the data. All the patients who gave their time to the study. CDL is supported by a grant received from Guy's and St Thomas' Charitable Foundation (no: R020216).

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Oral Oncology (2005) 41, 440–454

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REVIEW

Are psycho-social and behavioural factors related to health related-quality of life in patients with head and neck cancer? A systematic review

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Received 22 November 2004; accepted 8 December 2004

KEYWORDS
Review;
Head and neck cancer;
Health related quality of life;
Psychology

Summary The survival rate in advanced cancer of the head and neck has remained at approximately 50%, and efforts are now directed towards reducing the impact of the disease and its treatment in terms of functioning and health related-quality of life (HR-QoL). Factors such as stage, site of disease and type of treatment all impact on HR-QoL, but it is unclear what additional factors influence HR-QoL.

A systematic review was undertaken of studies that have investigated psycho-social or behavioural factors associated with HR-QoL in this patient group.

Literature was systematically searched using electronic databases and hand-searching relevant journals. Data were sought on HR-QoL and studies were only included if the measurement instrument was recognised as a reliable and valid measure of HR-QoL. Studies had to include at least one psycho-social or behavioural predictor variable.

Sixteen studies fulfilling the inclusion criteria were identified and reviewed. Five main factors were associated with varying degrees with HR-QoL, personality, social support, satisfaction with consultation and information, behavioural factors, such as consuming alcohol and smoking, and depressive symptoms.

The major difficulty with synthesising the findings was the amount of different indices of QoL that have been used. However, a number of psycho-social factors have been investigated in relation to HR-QoL in head and neck cancer patients, some of which are potentially modifiable, such as those related to informational needs. Further research is needed to investigate other psychological factors which may influence aspects of HR-QoL. By understanding the relationship between

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1368-8375/$ - see front matter
doi:10.1016/j.oraloncology.2004.12.006

HR-QoL and potentially modifiable variables, interventions can be designed with the aim of improving a patient's long-term well-being.

Introduction

In 1998, there were 6500 incident cases in the UK of lip and mouth (including tongue), pharynx and larynx cancers, and 2700 deaths, equivalent to between seven and eight deaths per day.[1] Despite recent developments in reconstructive techniques and more sophisticated treatment regimes involving specialist multi-disciplinary teams, the survival rate in advanced disease has remained at approximately 50%. Continuing efforts such as conservation and reconstruction procedures, speech therapy and prostheses have been directed towards lessening the impact of the disease and its treatment in terms of disability and functioning.

Comprehensive assessment of the impact of head and neck cancer encompasses more than clinical outcomes such as survival and disease progression and even goes beyond level of functioning, to include patient well-being. The interest in quality of life (QoL) has increased in recent years and much has been published examining QoL issues in HNC patients.[2,3] There is wide variation in what is meant by QoL. The World Health Organisation has defined a high QoL as a 'state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.' Using the WHO's definition, global QoL could feasibly include a patient's psychological and emotional status and perceptions of satisfaction found in work, home life, religion, family, education or income. Assessing global QoL generally provides a broader picture of the impact of disease on an individual's life. In clinical practice, however, QoL generally refers to health-related quality-of-life (HR-QoL) which seeks to examine aspects of QoL thought to be impacted by a health or medical concern. Assessment of HR-QoL typically includes physical, psychological and social domains. Each domain may include measures that assess the patient's perception of symptoms, ability to function and disability.[4]

As it is accepted that 'HR-QoL' is a broad, multidimensional concept, a number of questionnaires have been developed that reflect this complex conceptual framework. There are three main categories of questionnaire that are commonly applied to assess the HR-QoL of HNC patients, performance questionnaires aside: global HR-QoL, general cancer HR-QoL and HNC specific HR-QoL. Global or generic questionnaires can be applied to patients with any disease or a 'normal' population and assess physical, psychological and social functioning (e.g., Short form Health Survey (SF-12);[5] General Health Questionnaire (GHQ)[6]). General cancer questionnaires focus on common symptoms and side-effects of cancer treatments (e.g., The European Organisation for Research and Treatment of Cancer (EORTC) core questionnaire;[7] The Functional Assessment of Cancer Therapy Scale (FACT-G);[8] Functional Living Index-Cancer Scale (FLIC)[9]). HNC specific HR-QoL questionnaires are intended to assess the specific impact of HNC and its treatment on an individuals HR-QoL in terms of oral function, which includes aspects of communication, swallowing, chewing, nutrition and cosmesis (e.g., The EORTC QLQ H&N35[10]).

HR-QoL has been found to vary over time and with treatment modality in head and neck cancer patients.[11,12] However, there is a poor understanding of the reasons why people at similar stages of the disease who have also received similar treatments experience different levels of quality of life. Accumulating research evidence has revealed that there is enormous variation in the ways patients adjust to illness and the nature of this adjustment is crucial in determining both psychological and physical health outcomes. There is also consistent evidence that this variation is not primarily due to clinical factors such as illness severity.

The primary value of understanding individual variation in HR-QoL is to minimise the impact of HNC on a patient's life. By understanding the relationship between HR-QoL and potentially modifiable psychological factors interventions can be designed with the aim of maximising a patient's long-term HR-QoL. To gain a better understanding of what additional factors have been assessed in relation to HR-QoL in HNC a systematic review was undertaken.

The systematic review sought to answer the following research questions:

(1) What psycho-social or behavioural factors are associated with HR-QoL?

(2) What is the relationship between depressive symptoms and HR-QoL?

Methods

Search techniques and terms

Databases

An electronic search was undertaken of 10 databases: MEDLINE, CANCERLIT, CINAHL, EMBASE, PsycINFO, the Institute for Scientific Information (ISI) databases of Science Citation Index Expanded (SCI-EXPANDED) and Social Sciences Citation Index (SSCI) via the Web of Knowledge (WOK). Recent journals that may not have entered the electronic system were also hand-searched (Cancer, Head and Neck; Journal of Clinical Oncology; Laryngoscope; International Journal of Oral and Maxillofacial Surgery; British Journal of Oral and Maxillofacial Surgery; Otolaryngology Head and Neck Surgery; Quality of Life Research, Psycho-Oncology). An attempt was also made to identify any peer-reviewed but unpublished work by asking leading researchers/clinicians in the field.

Search terms

Two search strategies were conducted on each database separately, based on searching subject headings (i) and a free-text search (ii), these were then combined using the Boolean operator 'OR'. (Specific search terms are listed in Appendix A.) The searches were limited by including only literature published in the English language between the years 1980 to present and only involving human participants. The year of 1980 was considered a good cut-off point due to the relative recency of literature on quality of life. All commentaries, editorials, case-reports and review articles were excluded.

Study inclusion criteria

Outcome measures

Data were sought on HR-QoL and studies were only included if the measurement instrument was either recognised as a reliable and valid measure of QoL. Assessment of HR-QoL typically includes physical, psychological and social domains, therefore, measures of purely functional status were not included. Instruments such as the Hospital Anxiety and Depression Scale (HADS) and measures of disfigurement were also not considered measures of HR-QoL for the purposes of this review.

Data extraction and synthesis

Data were extracted from full-version articles using pre-designed tables to ensure that data extraction was standardised. Disease characteristics of the patient, (i.e., site and type of cancer, treatment type and outcomes) were too heterogeneous to apply formal meta-analytical pooling. Individual studies were reported separately, with their specific design features and results, in accordance with accepted guidelines from the NHS Centre for Reviews and Dissemination.[13]

Critical appraisal of study quality

Each of the studies was scored for quality on six criteria. These included the study aims or research question, study design, sample characteristics, statistical analysis, statistical power and validity of conclusions. Each factor was valued on a three-point scale with 0 indicating poor, 1 for adequate and 2 for good and an overall score for the study was thus calculated by summing these out of a possible total score of 12 points (see Appendix B for definitions).

Results

A total of 16 studies fulfilling the inclusion criteria were identified and reviewed. The final selection of studies showed wide variation in terms of the aspects of QoL that were assessed, patient sample and study design. Key data are summarized in Tables 1 and 2. Four main factors were identified in relation to HR-QoL in HNC patients. The results are discussed below under the main headings of Personality, Social support, Satisfaction with consultation and information, and Behavioural factors. The relationship between depression and HR-QoL has been considered separately due to the debate that depression may simply reflect a dimension of QoL, and includes studies that have analysed the extent to which depressive symptoms affect HR-QoL as well as vice versa.

Personality

Personality may be defined as a person's characteristics that are responsible for relatively stable patterns of feeling, thinking and behaviour.[14] There are many ways of conceptualising and measuring personality 'traits' however but few have been investigated as potential influences on HR-QoL in

Table 1 Summary of variables studied in relation to HR-QoL

Variable	Specific component	Study
Personality	• Neuroticism and extraversion	15
	• Dispositional optimism	18,19,21
Social support	• Satisfaction with family physician support	23
	• Extent of social contact with family, friends, neighbours	17
Information	• Satisfaction with information and consultation	21
Risk behaviour	• Alcohol	27–29
	• Smoking	29,34
Mood	• Depression	17,29,34,38,41,42,44,46,53

HNC. Four studies were identified that attempted to examine this relationship.

Neuroticism and extraversion

A recent cross-sectional study by Aarstad et al.[15] demonstrated an association between personality, as measured by The Eysenck Personality Questionnaire[16] and HR-QoL (EORTC QLQ-C30 + HN35) in two different samples of successfully treated primary HNC patients. The patients consisted of one sample of 96 HNC patients and another sample of 104 laryngectomised patients, also discussed later in the review, in a study by Birkhaug et al.[17]

Aarstad et al.[15] found that high neuroticism was associated with a lower HR-QoL in both patient samples. Specifically, neuroticism was negatively correlated with cancer specific HR-QoL,[7] and positively correlated with the majority of general cancer symptom scales in both samples, and with the majority of head and neck cancer specific scores[10] in the laryngectomised sample only. These associations were reported as stable after adjustments were made for gender, age, marital status, educational level, number of children and level of treatment. Significant positive associations were found between extraversion scores and general health/QoL, demonstrating that higher extraversion scores were associated with better QoL functioning.

Dispositional optimism

The role of dispositional optimism on HR-QoL in HNC patients was assessed in three papers, but was the primary focus of only two.[18,19]

In a prospective study by Allison et al.,[18] dispositional optimism was associated with better HR-QoL in a consecutive sample of 101 French HNC patients. The sample consisted of oral, pharyngeal and laryngeal cancer patients and measures were taken at baseline and three months following treatment. The dependent variable of HR-QoL was measured using a cancer specific HR-QoL measure only (EORTC QLQ-C30) and optimism was evaluated using a French version of the Life Orientation Test (LOT).[20] Optimism scores were dichotomised around the median, and in multi-variate analyses of the pre-treatment data, the dichotomised LOT rating significantly predicted HR-QoL domains of role, cognitive and emotional functioning; global HR-QoL; pain and fatigue, whilst adding treatment as another independent variable and controlling for disease site and stage. A similar result was gained from multi-variate analyses conducted on three-month follow-up HR-QoL data. Bivariate analyses indicated that 'optimistic' patients were more likely to report better HR-QoL than 'pessimists', however, specific results from the multi-variate analyses were not reported.

In a repeated measures design study by Yu et al.,[21] the association between satisfaction with information and QoL in 211 nasopharyngeal cancer patients was examined. In addition to these main variables of interest, trait optimism was included as part of a battery of psychosocial variables. Optimism was measured using a single visual analogue line. HR-QoL was measured with the Chinese version of the Functional Assessment of Cancer Therapy—General Scale: FACT—G (Ch).[22] Optimism at follow-up Time 1 (at the completion of radiotherapy but 4 months post-baseline) was initially found to be a significant predictor of HR-QoL 4 months later (8 months post-baseline), in addition to variables of 'satisfaction with the information provided', 'worry about family', treatment and recurrence after baseline. However, after adjusting for baseline QoL scores, optimism became insignificant.

In the same patient group,[19] the mediating role of optimism between eating ability and post-radiation QoL was investigated with a series of regression analyses, and adjusting for baseline HR-QoL scores, family income (as a measure of economic

Table 2 Summary of study characteristics

Author Year (Country of study)	Study design[a]	Time-points of follow-up	Sample[b]	Dependent variables (DV)[c]	Psycho-social/ behavioural independent variables (IV) included	Overall study quality[d]
Aarstad et al., 2003 (Norway)	X-S	n/a	*n = 96* (H&N) Mean age at study 61 yrs (sd = 11); time since diag. = 4 yrs (sd = 2); 78% male (T = mixed) *n = 104** (Larynx, all S) Mean age at study 66 yrs (sd = 10); time since treat. = 10 yrs (sd = 7); 86% male (*Same data set as Birkhaug et al., 2002)	*n = 31* • HR-QoL: EORTC QLQ −C30 + H&N35(+ 3 cluster scores as Birkhaug et al., 2002)	• Personality (Neuroticism, Extraversion and lie scales)	Adequate
Nordgren et al., 2003 (Sweden and Norway)	P	Diag, 1, 5 yrs post-treat.	*n = 86* (Larynx) *n* = 74 at 1 yr, *n* = 53 at 5 yrs. 84% male; 15% S; 64% stages I/II; mean age 66 (21–88) (all RT)	*n = 1* • HR-QoL: EORTC QLQ-C30 (global QoL)	• Depression	Adequate
Yu et al., 2003 (China)	P	Pre-, 4 (F1) and 8 mths (F2) (*n* = 187)	*n = 211** (nasopharynx) Mean age 49.7 yrs (sd = 12.2) 74% male (all RT) (*Same data set as Yu et al., 2001)	*n = 1* • HR-QoL: FACT-G (Chinese v, sum score)	• Personality (Optimism) • Eating ability	Good
Allison, 2002 (Canada)	X-S	n/a	*n = 191* (H&N) Mean age at study 64.1 yrs (med = 64; 29–92); mean time since treat. = 28.1 mths (med = 14; 0–168); 73% male (T = mixed)	*n = 28* • HR-QoL: EORTC QLQ-C30 + H&N35	• Alcohol	Adequate
Birkhaug et al., 2002 (Norway)	X-S	n/a	*n = 104* (Larynx) Mean age 66 yrs (sd = 10) mean time since treat. = 10 yrs (sd = 7); 84% male (all S)	*n = 3* • HR-QoL: EORTC QLQ-C30 + H&N35: (1. functional and general scales (C30); 2. symptom scales (C30) 3. H&N35 scales)	• Social support • Depression	Adequate
Duffy et al., 2002 (USA)	X-S	n/a	*n = 81* (H&N) Mean age 62 yrs (40–84); 83% male (T = n/k)	*n = 12* • HR-QoL: SF-36V (8 scales), HNQoL (4 scales)	• Alcohol • Smoking • Depression	Adequate

Sehlen et al., 2002 (Germany)	P	Start, end and 6 wks post-RT	*n = 83* (H&N) Median age 59 yrs (25–81); 77% male (all RT)	*n = 1* • HR-QoL: FACT-G (v3; sum score. Dichotomised into 'low' and 'high' QoL)	• Alcohol abuse	Poor
De Leeuw et al., 2001 (The Netherlands)	P	Pre-, 6 mths, 1, 2 and 3 yrs later	*n = 197* (H&N) (*n* = 171 at 1 yr, 139 at 2 yrs, 123 at 3 yrs); mean age at diag. 59 yrs (sd = 10.6); 78% male; 80% RT; 57% (T = mixed)	*n = 4* • Depression: CES-D (total score at 4 time points)	• HR-QoL (Only EORTC QLQ-C30 + 3, subscales of: phys symptoms and phys func. +21 phys symptom items from H&N37 module used.) • Social support • Coping • Locus of control • Depression	Good
Hammerlid et al., 2001 (Sweden)	P	Pre- and 3 yrs	*n = 232* (H&N) (*n* = 184 at 3 mths, 160 at 1 yr, 133 at 3 yrs); mean age at diag. 61 yrs (18–85); 70% male (T = mixed)	*n = 3* • HR-QoL: EORTC QLQ-C30 and H&N35/37, 1. Global HR-QoL, 2. emotional functioning, 3. H&N35 pain		Poor
Yu et al., 2001 (China)	P	Pre-, 4 (F1) and 8 mths (F2) (*n* = 187)	*n = 211* (nasopharynx) Mean age 49.7 yrs (sd = 12.2) 74% male (all RT)	*n = 1* • HR-QoL: FACT-G (Chinese v; sum score)	• Satisfaction with consultation/ information • Satisfaction with hospital services • Worry about family • Anger • Personality (Optimism)	Good
Allison et al., 2000 (France)	P	Pre- and 3 mths posttreat. (*n* = 88)	*n = 101* (H&N) Mean age 58.2 yrs (sd = 11.6) 93% male (T = mixed)	*n = 15* • HR-QoL: EORTC QLQ-C30 (5 funct. scales, 1 global rating and 9 symptom scales)	• Personality (Dispositional optimism)	Good

Table 2 (*continued*)

Author Year (Country of study)	Study design[a]	Time-points of follow-up	Sample[b]	Dependent variables (DV)[c]	Psycho-social/ behavioural independent variables (IV) included	Overall study quality[d]
De Graeff et al., 2000a (The Netherlands)	P	Diag, 6 mths, 1 yr	*n = 153** (H&N) Age range 29–76 yrs; 80% male (T = mixed) (*Same dataset used for later analysis, De Leeuw et al., 2001 and De Leeuw et al., 2000)	*n = 16* • HR-QoL: EORTC QLQ-C30 and H&N35	• Depression	Good
De Leeuw et al., 2000 (The Netherlands)	P	Diag, 6 mths, 1 yr	*n = 155** (H&N) Mean age = 59 yrs (sd = 10.8); 79% male (T = mixed) (*Same dataset used for later analysis, De Leeuw et al., 2001 and De Graeff, 2000a)	*n = 2* • Depression: CES-D (total score at 2 time points)	• HR-QoL (Only EORTC QLQ-C30+3, subscales of phys symptoms and phys func. + 21 phys symptom items from H&N37 module used.) • Social support • Coping • Locus of control	Good
Gritz et al., 1999 (USA)	P	Pre-, 1 and 12 mths post	*n = 105* (H&N) Mean age 58.4 yrs (sd = 9.2) 70% male (T = mixed)	*n = 6* • HR-QoL: CARES-SF (5 domain scores and overall score)	Mood states: • Tension–anxiety • Depression–dejection • Anger–hostility • Confusion–bewilderment • Fatigue–inertia • Vigor–activity • Smoking	Good
D'Antonio et al., 1998 (USA)	X-S	None	*n = 50* (H&N) • (from 6 mths to 6 yrs post-surgery) 76% male; mean age at study = 62 yrs (38–82); 74% = ND; 26% stages I/II (T = mixed)	*n = 9* • HR-QoL: FACT (FACT-G and FACT-HN) UW-QoL (total)	• Depression	Poor

Mathieson et al., 1996 (Canada)	X-S	n/a	n = 45 (H&N) Mean age = 61 yrs; time since diag. range from <6–>60 mths 73% male (T = n/k)	• HR-QoL: FLIC (composite score) • Social support (measured on 5 dimensions)	n = 1

[a] X-S = Cross-sectional study design; P = prospective study design.
[b] RT = Radiotherapy treatment; S = surgery, 'T = n/k' indicates treatment modality data not collected, 'T = mixed' indicates that treatment data has been collected for both.
[c] If tests of association only were conducted, or unless specified, the HR-QoL score was tabulated under the dependent variable headed column and other variables of interest were included under the independent variable headed column for simplicity. The EORTC QLQ-C30 + H&N35 = The European Organisation for Research and Treatment of Cancer QLQ-C30 and Head and Neck module; SF-36V = Short form-36 Veterans version; HNQoL = The Head and Neck Quality of Life; FACT-G = Functional Assessment of Cancer Therapy-General Scale; SF = Cancer Rehabilitation Evaluation System-Short form; FLIC = Functional Living Index-Cancer scale, CES-D = Centre for Epidemiologic Studies-Depression scale.
[d] Overall quality score derived from sum of scores from six factors each scored 0–2 (see Appendix B for factors and score definitions). Those scoring between 0 and 4 = poor; 5 and 8 = adequate; 9 and 12 = good.

status) and cancer stage at baseline. The results indicated that eating ability at the completion of radiotherapy was independently predictive of both optimism and QoL 4 months later. However, this relationship was no longer significant when optimism was controlled for. These data suggest that optimism was exerting a mediating effect between the two variables.

Social support

Two cross-sectional studies analysed the impact of social support on HR-QoL.[17,23] In the earlier study of 45 patients by Mathieson et al.,[23] social support was measured using the Social Support Questionnaire (SSQ).[24] The results of a regression analysis with HR-QoL as the dependent variable (derived from the Functional Living Index-Cancer scale (FLIC)), showed four main factors predicted quality of life. Satisfaction with family physician support was a significant predictor together with severity of cancer; gender and site of cancer.

In contrast, in a study by Birkhaug et al.,[17] social support was not found to be associated with QoL in 104 patients with cancer of the larynx. All of the patients had undergone surgery and the majority of these patients had received radiation therapy. Social support was measured using an inventory consisting of 15 questions in which the respondent was asked to indicate the extent of social contact with family, friends and neighbours.[25] HR-QoL (EORTC QLQ-C30 + HN35) was collapsed into three dependent variables of functional and general scales; symptoms and H&N35 items. Regression analyses were adjusted for age and gender. No significant relationship was determined between HR-QoL and the amount of reported social support.

Satisfaction with information and consultation

The association between satisfaction with information and QoL was assessed in a sample of patients with nasopharyngeal cancer (NPC) undergoing radiotherapy (referred to earlier).[21] Predictor variables were measured using the Medical Interview Satisfaction Scale (MISS),[26] which measured patients' satisfaction with the way in which physicians provided information, and comprised cognitive, affective and behavioural subscales, including a 5-item cognitive subscale with items selected based on their relevance to NPC patients. Forced entry multiple regression models indicated

that QoL at Time 2 (8 months after referral) was predicted by the five-item cognitive subscale of the MISS. This suggested that NPC patients reporting more satisfaction with the information provided approximately 1 month after the end of radiotherapy, had a better QoL 4 months later. Optimism and worry at time 1, treatment and recurrence after baseline, were also found to significantly predict QoL at Time 2. However, when baseline QoL and stage of disease at time of diagnosis were adjusted for, the most significant predictor remained the patient's satisfaction with information. Worry, treatment and recurrence after baseline also remained significant and all other variables, including optimism, were found to be insignificant.

Behavioural factors associated with HR-QoL: alcohol consumption and smoking

Three recent studies have investigated the relationship between alcohol intake and HR-QoL in HNC patients, with differing results. Allison[27] conducted a cross-sectional survey of 191 patients with either carcinoma of the oral cavity, pharynx or larynx. Alcohol intake was measured with a single item question, 'during the past month have you drunk alcohol on one or more occasions?' The results from multi-variate regression analyses showed that alcohol consumption was significantly associated with EORTC QLQ-C30 + HN35 domains of physical functioning, role functioning, global HR-QoL, fatigue, pain, swallowing, dry mouth and feeling ill, whilst controlling for age, gender, employment status, disease site and stage, time since treatment and treatment modality. Data indicated that patients consuming at least one alcoholic drink in the past month had better HR-QoL functional scores and lower levels of symptoms than participants reporting no alcohol intake. However, the results presented in the paper lack the detail to make any more assumptions regarding these relationships.

In contrast, in a prospective study by Sehlen et al.,[28] excess alcohol consumption was found to be associated with worse HR-QoL. A sample of 83 patients with HNC were assessed with the FACT-G questionnaire prior to radiotherapy, at the end of radiotherapy and six weeks after. Socio-demographic variables were measured with the Current Situation in Personal Life questionnaire, which was developed by the authors. Patients with a Karnofsky performance status score of <50 were excluded from recruitment. Binary logistic regression models were used with the FACT-G sum score dichotomised into low (<70) and high HR-QoL (>70). After testing various models based on medical and socio-demographic variables, having children, current employment, alcohol abuse, level of secondary education and gender were found to account for a quarter of the variance in HR-QoL six weeks after radiotherapy. On examination of the odds ratios, patients with no or low secondary education had a four-fold higher risk of having a low HR-QoL than patients with medium secondary education and an eight to nine-fold higher risk than patients with a high education. Male patients were at a higher risk of low HR-QoL, as were patients without children and unemployed. However, it was found that those at highest risk of low HR-QoL were patients reporting alcohol abuse. The confidence intervals were not reported which, again, makes it difficult to ascertain their significance.

In contrast to both of the above studies, Duffy et al.,[29] failed to find any relationship between alcohol intake and HR-QoL (SF-36V and HNQoL,[30,31]) although a significant relationship between smoking and HR-QoL was found. Alcohol was measured with the Alcohol Use Disorder Identification Test (AUDIT)[32] which is a 10-item screening instrument that assesses both level of alcohol intake and related problems, including hazardous drinking, alcohol abuse and dependence. Smoking was measured with the Fagerstrom Test for Nicotine Dependence (FTND)[33] which is a six-item questionnaire. Smoking was found to be negatively associated with five scales of the SF-36V[30] physical functioning, general health, vitality, social functioning and role-emotional health, however, alcohol was not associated with any of the HR-QoL scales. However, a 12-month prospective study involving 105 HNC patients by Gritz et al.,[34] failed to find any relationship between current smoking (smokers vs. quitters) and global HR-QoL. Patients were originally recruited as part of a larger randomised controlled trial comparing two differently delivered smoking cessation programmes and as such the paper only included patients who had reported tobacco use within the last year prior to diagnosis. HR-QoL was measured using the Cancer Rehabilitation Evaluation System-Short Form (CARES-SF)[35] which is a generic cancer measure that yields a global score and five summary scores (physical, psychosocial, marital, sexual and medical interaction).

Depressive symptoms

Nine papers examined the relationship between depressive symptoms and HR-QoL. Three of these

used cross-sectional designs and the others were prospective studies with short and longer-term outcome assessments. In addition, two further prospective studies examined the relationship between depression and HR-QoL using depression as the outcome (dependent) measure. These three groups have been presented separately below.

Cross-sectional studies

Significant relationships between depressive symptoms and HR-QoL were found in all three of the cross-sectional studies. Duffy et al.,[29] used the Geriatric Depression Scale-Short Form (GDS-SF)[36] to assess levels of depression in a mixed sample of 81 HNC patients and found that nearly half had significant depressive symptoms. HR-QoL was measured using the SF-36V[30] and the HNQoL.[31] All 12 multiple regression analyses indicated strong negative associations between significant depressive symptoms and HR-QoL, when controlling for age, tumour site and stage, nicotine and alcohol problems.

Similarly, Birkhaug et al.,[17] found that 35% of patients, on average 10 years since treatment, reported either possible or probable depression using the Beck Depression Inventory (BDI).[37] Significant negative correlations existed between all HR-QoL functional scales, global health/QoL score and depression, indicating that the lower the HR-QoL, the higher the depression.

An earlier study by D'Antonio et al.,[38] of 50 patients evaluated from 6 months to 6 years post-surgery, also found an inverse relationship between HR-QoL, as measured by the FACT-G, FACT-HNS and the UW-QoL scales, and depression (BDI). Using the full version of the BDI, 22% of the sample demonstrated moderate to severe levels of depression. There were no relationships reported between the clinician evaluation of a patient's emotional well-being and the patient's score of emotional well-being (derived from the FACT-G) or depression. All analyses were uni-variate, therefore, no adjustments for other factors were made.

Prospective studies

The relationship between depression and HR-QoL during the first year post-treatment was reported in two papers.

De Graeff et al.,[39] revealed a predictive relationship between depression and HR-QoL (EORTC QLQ-C30 + HN35) in a sample of 153 HNC patients. The total amount of variance explained by depression was slightly greater for the prediction of head and neck specific scales than for the general cancer scales. Overall, depression, tumour stage and Karnofsky performance status were the most important predictors of HR-QoL.

However, another 12-month prospective study involving 105 HNC patients by Gritz et al.,[34] failed to find any relationship between depressive mood and HR-QoL (CARES-SF). Depressive mood was measured as part of the Profile of Mood States (POMS) scale.[40] The Depression–Dejection factor from the POMS reflects sadness, guilt, emotional isolation, worthlessness and futility. The results of multi-variate analyses showed that only treatment type, and HR-QoL at one month, were predictive of HR-QoL at 12 months.

The prospective relationship between depressive symptoms and HR-QoL, as an outcome measure, over a longer period, has been investigated in only two studies.[41,42] Hammerlid et al.,[41] reported significant relationships between depressive symptoms (HADS[43]) and HR-QoL (EORTC QLQ-C30 scales of Global QoL, emotional functioning and an H&N35 item of pain) in 133 patients (57% of the original sample) at 3 years post-treatment. It is unclear what percentage of total eligible patients the recruited sample represented.

In contrast, Nordgren et al.,[42] failed to find any relationship between baseline depression (HADS) and HR-QoL (EORTC QLQ-C30 + HN35) 5 years after diagnosis, in a sample of patients with cancer of the larynx.

Depression as an outcome variable

The role of HR-QoL in predicting depression was examined in two papers based on the same dataset. De Leeuw et al.,[44] collected data on 155 HNC patients at 6 and 12 months following treatment, in order to assess whether pre-treatment factors, including HR-QoL, could be used to predict depression at these time points. HR-QoL was represented by three scales of general cancer related physical symptoms derived from 12 items from the EORTC QLQ-C30 + 3, the Physical Functioning scale and head and neck tumour specific and treatment related physical symptoms derived from the 21 items of the EORTC QLQ-H&N37.[45] Social support, coping and locus of control were also measured as predictive variables. Stepwise multiple regressions were conducted to predict depression at 6 and 12 months post-treatment, entering tumour stage, age, gender, depressive symptoms at baseline, coping, cancer locus of control, support, the extent of social network, openness to discuss cancer in family, current HR-QoL (as represented by, general cancer related physical symptoms, tumour and treatment related physical symptoms and Physical Functioning). Two-thirds of the variance

in depressive symptoms was explained by these factors at 6 months and a half at 12 months. In addition to tumour stage and gender, current HR-QoL explained half of the variance at 6 months. Psychosocial variables measured prior to treatment explained an additional 12% of the variance (depressive symptoms, avoidance coping and the extent of formal social network). However, it is clear that most of this variance was from levels of depression prior to treatment.

Unsurprisingly, a similar relationship also emerged from another study by de Leeuw et al.,[46] reporting a slightly higher recruitment rate of 197 patients with 6 months post-treatment data and 171 patients with 12 months post-treatment data. Again, it was demonstrated that depressive symptoms prior to treatment were the best predictor of depressive symptoms at each time point. Data from 139 patients 2 years post treatment and 123 patients 3 years post-treatment, indicated that depression at those time points was mostly explained by baseline (pre-treatment) depression. HR-QoL could explain a further 20% approximately. Patients who had a recurrence during this time-period were not excluded from analyses.

Limitations

Study design and quality

The majority of studies included in this review are limited by methodological and statistical problems or missing data. However, seven of the studies included in this report attracted the highest 'quality' score of 'good' (scores of at least 9 out of 12) when critically appraised according to the criteria (Table 2). Three studies were deemed to be of a 'poor' quality (scores of between 0 and 4). The majority of studies did not forward any specific hypotheses for testing and all of the studies lacked any hypothetical or theoretical framework on which to base their research questions.

The studies varied in sample sizes and response rates, ranging from sample sizes of 45[23] to 232.[41] Response rates for the studies ranged from 45% of the original number of patients eligible for inclusion[19,21] to 99%,[18] however, many of these were based on convenience samples and recurrent cancer patients and in many studies the exact number of patients eligible for inclusion at the time of the study has not been reported, therefore, the response rates cannot be ascertained. This limits the ability to generalise from these studies.

Health-related quality of life as an outcome measure

The majority of the studies used the EORTC QLQ-C30&HN35 to assess HR-QoL. However, many different dependent (or outcome) variables were selected to measure relationships between variables. The lack of concordance between results may have been due in part to using different measures of HR-QoL or using different subscales of the same measure. For example Mathieson et al.,[23] used a composite score from a general measure of HR-QoL in cancer patients and Birkhaug et al.,[17] used both general cancer and head and neck cancer specific scales in their assessment of the relationship between HR-QoL and social support. In addition, studies used different methods of data collection.

Statistical limitations

In many studies it was difficult to ascertain how results had been statistically derived from the data. Many of the studies relied on uni-variate analyses and did not control for variables already known to be potentially confounding (e.g., various socio-demographic and medical/treatment factors). HR-QoL at baseline was not always adequately controlled for when analysing data from prospective studies.

It was unclear whether much of the data published met assumptions for parametric testing and the general lack of detail made it difficult to determine whether variables entered into regression models were statistically appropriate. Authors rarely mentioned whether skewed data had been transformed before analyses. Similarly, there was a general lack of detail regarding missing data and how this was dealt with before analyses. Despite the small sample sizes generally recruited in the field of head and neck cancer, few of the studies reported actual power calculations or provided comment about the power of study based on their method of analyses.

Discussion

Health related quality of life is now considered an important patient centred outcome variable following treatment for head and neck cancer. This has lead to a dramatic increase in the number of studies incorporating assessments of HR-QoL. Despite this increase in interest, the majority of stud-

ies investigating HR-QoL in this population have mainly been aimed at comparing the impact of different treatment modalities and have therefore only commented upon the effects of treatment and disease related variables. This has resulted in knowledge about the effects of disease site and treatment on HR-QoL, however, few studies have attempted to explore the impact of non-clinical variables on HR-QoL.

The limited data regarding the role of personality traits on reported HR-QoL indicated significant predictive and associative relationships. All four studies examining trait characteristics of either neuroticism/extraversion or optimism were considered 'adequate' or 'good' in quality.[15,18,19,21] Results demonstrated that the higher the extraversion or optimism score of the patient, the higher they rated their HR-QoL. In contrast, patients scoring highly for neuroticism were more likely to have a low HR-QoL. Personality is thought to influence health outcomes either directly or indirectly through a number of mechanisms, including symptom reporting[47,48] and coping styles. Dispositional optimism has been found to correlate positively with problem-focused coping, the positive reinterpretation of a problem and the attempt to accept the reality of situations that are perceived to be uncontrollable.[20] Coping may be an important mediator between personality and outcome and thus may be more open to psychological intervention than directly targeting relatively stable personality traits.[49]

The role of social support on HR-QoL is less clear. Of the two 'adequately' rated cross-sectional studies, one study failed to find any relationship between the 'extent of social support from family, friends and neighbours' and HR-QoL,[17] whereas, another study demonstrated that 'satisfaction with physician support' accounted for 45% of the variance in HR-QoL.[23] The 'support' assessed in these two instances illustrates not only the wide differences in underlying construct between different types of social support measure but of the subsequent implications that arise from employing different types of support measure. Interestingly, the study finding no relationship between level of support and HR-QoL involved laryngectomy patients who may have more complex issues involving communication, social support needs and subsequent HR-QoL. Social support is a complex interactive construct, which may only be effective when matched with the patients needs. Studies also confirm that it is the perceived quality of the social support that affect outcomes such as well-being and depression.[50] It is these components of support which need to be explored in more detail in future work in order to have a clearer understanding of their possible effects on QoL.

Alcohol and nicotine usage were found to be associated with HR-QoL in two ways. An 'adequately' rated cross-sectional study by Allison, found having had at least one alcoholic drink in the past month (post-treatment) was associated with higher levels of HR-QoL. This may have been due to better functional ability in swallowing and drinking rather than alcohol per se influencing HR-QoL. In a 'poorly' rated study by Sehlen et al.,[28] excess alcohol was associated with a worse HR-QoL, which may have been representative of worse disease and an addiction to alcohol. Similarly, Duffy et al.,[29] found a negative relationship between nicotine dependence and HR-QoL, demonstrating that those with a high dependence to nicotine reported worse HR-QoL. The scope for providing support and intervention in treating addictions such as these for particular at risk patients would be beneficial not only in terms of an individual's QoL but also to limit the chance of cancer recurrence in the future, as alcohol and tobacco are well known aetiological agents of HNC.

A fairly consistent picture emerges from the literature regarding the relationship between depressive symptoms and HR-QoL. Of the nine studies included in this review, seven reported significant relationships between depression and HR-QoL,[11,17,29,38,41,44,46] despite the range in quality ratings of the studies and the wide range of depression measures applied. For example, the BDI includes vegetative symptoms (loss of appetite, fatigue, lack of motivation etc.), which are attributable to depression, however, these symptoms can also be indicative of treatment side-effects or disease progress. This makes any relationship less easy to interpret. The HADS, on the other hand, does not contain any items that are related to physical conditions. Three of the studies reporting associations were cross-sectional in design and analyses were uni-variate, therefore direction of causation is unknown. Regarding depression as a predictor of HR-QoL, the results appear inconclusive as 2 out of 4 of the studies failed to find a significant relationship in either the short-term or the longer term. Of the two studies examining the role of HR-QoL on depression, it was found that although significant relationships existed, depression at baseline was a far better predictor of depression than current HR-QoL. These last two studies were rated highly as 'good', but were actually based on the same data set and similar analyses and, therefore, should not be taken as providing 'double' the support.

It is unsurprising that depression is related to HR-QoL, however, it is difficult to ascertain which has the overriding influence on the other, as the relationship between depression and HR-QoL is complex, dynamic and somewhat overlapping. The lack of consistency regarding the relationship between depression and other outcomes, not just HR-QoL, reflects a fundamental problem in all areas of the literature and not just HNC. This discrepancy also illustrates that lower HR-QoL may not necessarily lead to depressive symptoms or conversely that those who are depressed may have a relatively good HR-QoL compared to others. The underlying mechanism for this inconsistency may be due to adaptive or non-adaptive processes, such as 'burnout' as a result of long periods of stress[51] or adjustment to the illness and threat,[39] both of which may be related to mediational factors such as coping or effectiveness of support networks as mentioned previously. The relationship between physical symptoms/impairment and depression is far from understood. Further research is needed to unravel these relationships.

Recommendations

A number of key points emerge from this review. Arguably, there is a great need for more robust and theoretically-driven studies in this area. The main differences in HR-QoL between treatments and between cancer sites have now been defined and longitudinal patterns have been established, therefore, it is time to turn our attention to the predictors of HR-QoL and adaptation in order to develop appropriate interventions for change. Many interventions are now proceeding and failing without the robust empirical evidence or theoretical basis on which to base their content.[52] The need for reliable study designs and clear research questions based on theories which can be put into practice, are now of paramount importance if progression is to be made in this field. If potentially modifiable psycho-social factors are related to aspects of HR-QoL then these can be targeted with psychological intervention. Further research may elucidate which psychological factors would be best targeted, either for at risk groups or individuals at risk of poor outcome.

Acknowledgment

CDL is supported by a grant received from Guy's and St Thomas' Charitable Foundation (No. R020216).

Appendix A. Search terms

(i) For the subject heading search, the term 'head and neck cancer' was exploded to include the following subject index terms: neoplasms of head and neck, hypopharyngeal, laryngeal, nasopharyngeal, oropharyngeal, pharyngeal, tongue, tonsillar, esophageal, mouth, oral cavity, salivary gland, tracheal, submandibular gland and otorhinolaryngolic. This was combined with the subject heading 'Quality of life', which would also serve to include health related quality of life (HR-QoL) as a subject heading.

(ii) For the free text search, terms of Cancer$, carcino$, neoplas$, tumo?r$, 'head and neck', oral, mouth$, hypopharyn$, tongue, laryn$, naso$, oropharyn$, pharyn$, tonsil$, esophag$, oesophag$, salivary, tracheal$, submandibular$, otorhinolaryn$, quality of life, QoL, health state$, as text words (in title and abstract) were combined.

Appendix B. Critical appraisal of study quality

Factor	Score
Study aims/ Research question	Good (2): Aims clear, research Q or hypotheses stated Adequate (1): Aims stated, no specific research Q or hypotheses Poor (0): Aims not clear or not stated
Study design	Good (2): Prospective or case/ control Adequate (1): Cross-sectional Poor (0): Not clear
Sample characteristics	Good (2): Large, representative, well described Adequate (1): Limited info on sample or small and unrepresentative sample Poor (0): Unable to determine characteristics and representativeness of sample

Appendix B (*continued*)

Factor	Score
Analysis	Good (2): Appropriate multivariate analyses, controlling for confounding factors (esp.site/treatment if hetero sample) Adequate (1): Appropriate but limited/simplistic analyses Poor (0): Analyses inappropriate/ inadequate, likely to give misleading results
Statistical power	Good (2): Power calculation included or appropriately powered study Adequate (1): Adequately powered going by sample size/analyses Poor (0): v. Underpowered going by sample size/ analyses
Validity of conclusions	Good (2): Accurate and derived from good statistical analyses/design Adequate (1): Generally supported by results Poor (0): Bear no resemblance to results presented

Total score: Those scoring between 0 and 4 = poor, 5 and 8 = adequate, 9 and 12 = good.

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British Journal of Oral and Maxillofacial Surgery xxx (2005) xxx–xxx
BRITISH Journal of Oral and Maxillofacial Surgery
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Head and neck cancer: To what extent can psychological factors explain differences between health-related quality of life and individual quality of life?

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Accepted 24 June 2005

Abstract

Aims: To assess the extent to which individualised quality of life (QoL) was related to standardised health-related quality of life (HR-QoL), and to assess how much of the variation in each of these measures could be explained by psychological variables.
Methods: Fifty-five patients with newly diagnosed head and neck cancer completed the following outcome measures: the Patient Generated Index (PGI), the European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 and the Short Form 12 version 2 (SF-12v2). Explanatory factors were measured with the following: the Illness Perceptions Questionnaire-Revised (IPQ-R), the Beliefs about Medicines Questionnaire (BMQ), the Hospital Anxiety and Depression Scale (HADS), and the Brief COPE (a shortened version of the COPE).
Main findings: Standardised and individualised QoL measures were correlated only partly. The PGI correlated only with EORTC QLQ-C30 domains of emotional and cognitive functioning and SF-12 domains of mental health, emotional role, social, and physical role. The underlying psychological factors explaining each of the three outcome measures were different.
Conclusions: Respondent-generated measures such as the PGI could be used as an adjunct to more standardised measures of HR-QoL clinically. This has implications for assessing the impact of head and neck cancer on individualised QoL and also for improving patients' outcome through interventions aimed at targeting underlying psychological factors.

Keywords: Head and neck; Cancer; Quality-of-life; Psychology; Self-regulation

Introduction

In 1998, there were 6500 new cases of mouth and throat cancer in the UK, and 2700 deaths, between seven and eight deaths a day. Despite developments in treatment and reconstructive techniques the survival after advanced disease has remained at about 50%, and those who are cured incur considerable morbidity. Support services in the form of speech therapists, dieticians, and prosthetic practitioners have lessened the impact of disability and impaired functioning.

Assessment of the impact of head and neck cancer should encompass more than survival, and extends beyond functioning to include patient well-being. Recently, much has been published on QoL issues in patients with head and neck cancer, but there is wide variation in what is meant by quality of life. The World Health Organisation has defined a high QoL as a 'state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.' Using WHO's definition, global QoL should include a patient's psychological and emotional state and his or her satisfaction in work, home life, religion, family, education, and

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doi:10.1016/j.bjoms.2005.06.033

income. Assessing global QoL generally provides a broader picture of the impact of disease on a person's life. In clinical practice, however, QoL usually refers to health-related quality of life (HR-QoL) which examines aspects of QoL affected by a health or medical concern. Assessment of HR-QoL typically includes physical, psychological, and social domains, and tends to make the assumption that a standard set of circumstances is required for optimal well-being.

However, most assessments of HR-QoL do not take into account the fact that many patients have come to terms with their limitations and consequently these areas of measurement may have little impact on their extent of satisfaction. Within this context, there has been little published on the assessment of individualised QoL (how patients perceive their QoL with respect to areas most important to them) and how it compares with more standard measures.

The use of a theoretical framework: the self-regulation model

Standardised HR-QoL varies with time and treatment, but why those with similar stages of disease and treatment should experience different levels of quality of life is not clear. However, there is enormous variation in the way patients adjust to illness and the nature of this adjustment is crucial to psychological and physical outcomes. In addition, this variation is not primarily the result of clinical factors such as severity of illness. To gain a better understanding of how treatment of head and neck cancer influences QoL, a theoretical framework is required. The self-regulation model[1–3] (Fig. 1) shows how patients understand and adapt to a threat to their health. The framework suggests that four broad classes of factors influence patients' judgements and behaviour: the cognitive representation of the threat of the disease (the beliefs that patients have about their illnesses and treatment); the affective reaction (the emotional reaction to the illness); the coping mechanisms to deal with the threat and the emotions elicited by the threat; and contextual factors such as social roles and cultural and societal norms. We suggest that a patient's representation of a disease will affect the prominence, meaning, and importance of the domains involved in making judgements of QoL.[4] Specification of variables within this framework has led to the development of hypotheses to test and further our understanding of QoL in patients with head and neck cancer.

The aims of this study were two-fold: firstly, to assess the extent to which standardised and individualised measures of QoL were related to each other; and secondly, to assess the extent to which standardised and individual QoL before treatment can be explained by psychological variables, particularly those factors guided by the self-regulation model.

Three null hypotheses were tested:

There is no correlation between standardised assessments of HR-QoL and the individualised measure of QoL;
patients' beliefs about their illness and treatment will not explain a significant amount of variation in standardised HR-QoL; and
patients' beliefs about their illness and treatment will not explain a significant amount of variation in individualised QoL.

Methods

During the period July 2003 to March 2004, 55 patients who had recently been diagnosed with confirmed squamous cell carcinoma of the head and neck were recruited from four hospitals in the south-east of England, after obtaining approval from the Local Regional Ethics Committee and gaining patients' informed consent. Data were obtained during the period between confirmation of the diagnosis but before treatment, by self-completed questionnaires and medical records. Patients were recruited into an 8-month repeat measures study, but only (cross-sectional) data obtained before treatment are presented in this paper. Inclusion criteria were any patient over 18 years old with a newly diagnosed primary head and neck cancer.

Standard data that we recorded in this study were: age, sex, ethnicity, marital status, and educational attainment. Clinical

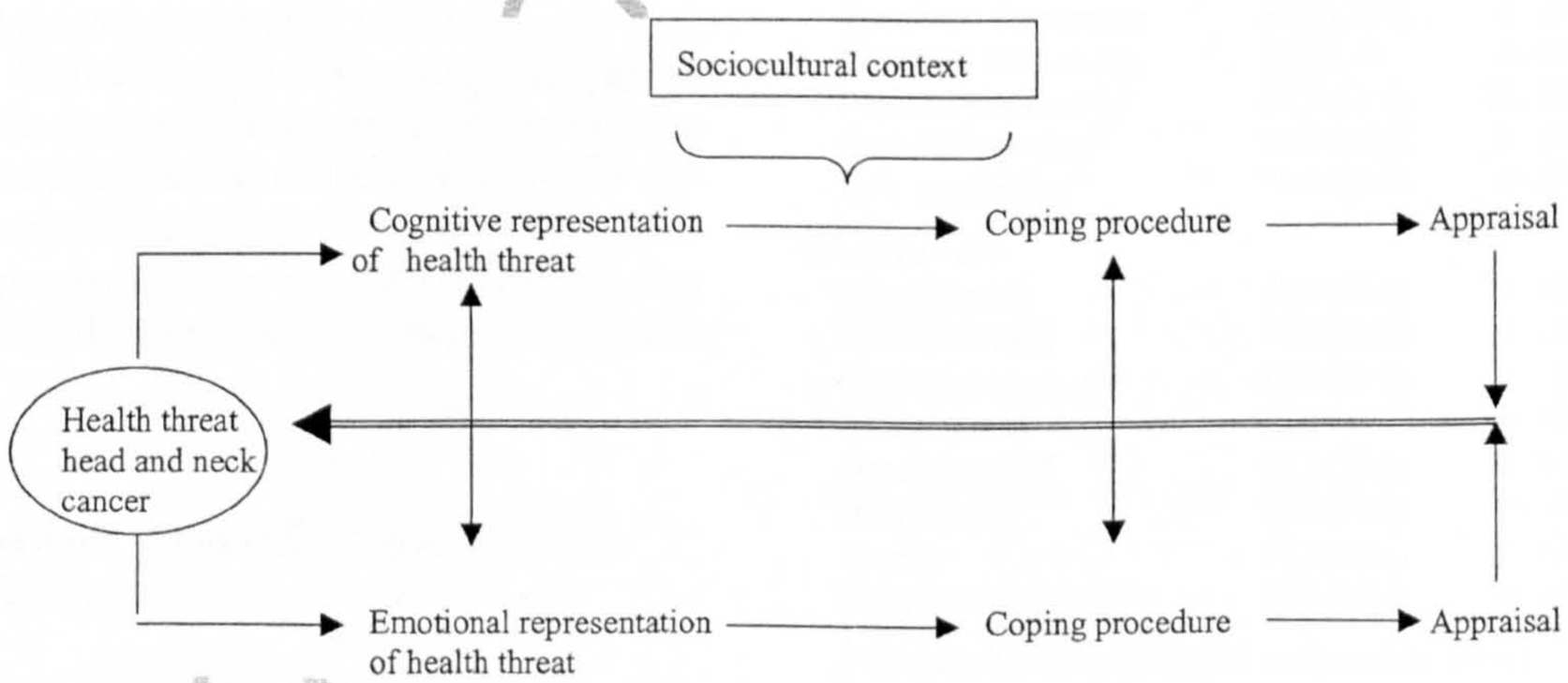

Fig. 1. The self-regulation model.

variables that were recorded were site, stage of disease, and type of treatment planned.

The details of the outcome instruments that we used are given in the appendix. They were: the European Organisation for the Research and Treatment of Cancer (EORTC) QLQ-C30,[5] The General Health Survey Questionnaire, Short Form 12 (SF-12v2)[6] and the Patient Generated Index (PGI).[7]

The following measures were used to assess psychological factors:

The Illness Perception Questionnaire-Revised (IPQ-R),[8] The Beliefs about Medicines Questionnaire-Specific Scale (BMQ-Specific),[1] The Hospital Anxiety and Depression Scale (HADS),[9] and the Brief COPE.[10]

Statistical analysis

Characteristics of responders and non-responders were assessed for differences using chi square tests for sex and stage of cancer, and an independent Student's *t*-test for age at diagnosis. Data on the three outcome measures were scored and standardised as per recommendations. Pearson's correlations were calculated among all the three outcome measures to assess any associations. Pearson's correlations were also calculated among all variables and each of the three outcome variables to establish correlations. Point biserial correlations were calculated for dichotomous variables (sex, marital status, and ethnicity) where significant correlations existed ($p < 0.01$), variables were then entered into multiple linear regression models using a stepwise entry method, to assess how much of the variation in each of the QoL measures could be explained by these independent variables.

Results

Patients' characteristics

The sample comprised 55 patients with newly diagnosed head and neck cancer, three quarters of those who had been invited to take part. There were 36 men (65%), which is typical of the disease, and the American Joint Committee on Cancer (AJCC) stages of disease were fairly evenly distributed (Table 1). Those who declined to take part tended to be older and there were more men, but the differences were not significant. There was also no significant difference in stage of cancer between responders and non-responders. The domains within the different QoL measures were internally reliable (Table 2).

The correlation between standardised HR-QoL and individualised QoL

Standardised HR-QoL and individualised QoL measures were correlated only partly (Table 3). The PGI correlated

Table 1
Characteristics of responders and non-responders

Characteristic	Responders ($n = 55$)	Non-responders[a] ($n = 18$)
Sex		
Male	36 (65)	12 (67)
Female	19 (35)	6 (33)
Age (years)		
Mean (S.D.)	59 (13.4)	61 (13.5)
Range	23–89	29–81
Ethnicity		
White	48 (87)	–
Other	7 (13)	–
Marital state		
Single/widowed	25 (45)	–
Married/cohabiting	30 (55)	–
Education[b]		
≤Secondary education	26 (47)	–
>Secondary education	26 (47)	–
AJCC Stage of cancer[a]		
Stage 1	11 (20)	3 (17)
Stage 2	11 (20)	4 (22)
Stage 3	9 (16)	2 (11)
Stage 4a	13 (24)	4 (22)
Stage 4b	0 (0)	3 (17)
Stage 4c	1 (2)	2 (11)
Treatment planned[a]		
Surgery only (S)	13 (24)	–
Radiotherapy only (RT)	16 (29)	–
S & RT	13 (24)	–
RT & Chemo. (CT)	5 (9)	–
S & RT & CT	2 (4)	–

Data are number (%) of patients.
[a] Data missing.
[b] Some data from non-responders were not available.

Table 2
Mean (S.D.), range and Cronbach's alpha values for the QoL measures

QoL domain	Mean (S.D.)	Range	Cronbach's α
PGI[a] ($n = 46$)	4.2 (2.3)	0–10	N/A
EORTC QLQ-C30 ($n = 55$)			
Global QoL/health[b]	63.4 (20.9)	0–100	0.8
Emotional functioning	67.6 (25.0)	0–100	0.9
Cognitive functioning	77 (28.4)	0–100	0.8
Physical functioning[b]	87.2 (17.7)	27–100	0.7
Social functioning[b]	75.1 (25.8)	0–100	0.7
Role functioning[b]	78.4 (29.4)	0–100	0.8
SF-12 ($n = 55$)			
Mental health	62.9 (21.2)	0–100	N/A
Role emotional	74.1 (28.9)	0–100	0.9
Social functioning[a,b]	74.5 (29.3)	0–100	N/A
Role physical	69.8 (27.7)	0–100	0.86
General health[a]	62.7 (25.9)	0–100	N/A
Bodily pain[a]	75.4 (31.0)	0–100	N/A
Vitality[a]	47.3 (26.6)	0–100	N/A
Physical functioning[b]	79.6 (29.2)	0–100	0.8

[a] Cronbach's alpha cannot be computed as overall QoL consists of only 1 final score.
[b] Data for 1 case missing.

Table 3
Correlations between individualised QoL and standardised HR-QoL measures

HR-QoL Domain	PGI (individualised QoL) $n=46$	
	Pearson's r	p-value
EORTC QLQ-C30		
Global QoL/health	0.46	<0.001
Emotional functioning	0.32	<0.05
Cognitive functioning	0.37	<0.01
Physical functioning	0.04	>0.05
Social functioning	0.15	>0.05
Role functioning	0.22	>0.05
SF-12		
Mental health	0.42	<0.005
Role emotional	0.48	<0.001
Social functioning	0.33	<0.05
Role physical	0.30	<0.05
General health	0.15	>0.05
Bodily pain	0.19	>0.05
Vitality	0.09	>0.05
Physical functioning	−0.12	>0.05

significantly only with EORTC QLQ-C30 domains of: emotional functioning ($r=0.320$, $p<0.05$); cognitive functioning ($r=0.368$, $p<0.01$) and global QoL/health ($r=0.464$, $p<0.001$), and similarly with SF-12 domains of: mental health ($r=0.421$,$p<0.005$); role emotional ($r=0.476$, $p<0.001$); social functioning ($r=0.334$, $p<0.05$) and role physical ($r=0.304$,$p<0.05$). This suggests that, before treatment, patients' priorities were less concerned with physical functioning and more with emotional and cognitive well-being.

The two standardised HR-QoL measures were highly correlated with each other.

Regression models examined the extent to which independent factors could explain variations in QoL (Tables 4–6). The main findings were:

Individualised QoL

Only psychological factors significantly explained variation in PGI scores (Table 4). Illness identity from the IPQ-R and the adaptive coping strategies of acceptance and use of instrumental support (Brief COPE) together explained 30% of the variation in PGI ($F=7.39$; d.f.$=3,41$; $p<0.01$).

Table 4
Variation in individualised QoL (PGI) explained by independent variables ($n=45$)

Explanatory factor	β
Illness identity (IPQ-R)	−0.30**
Acceptance (COPE)	−0.38*
Use of instrumental support (COPE)	−0.38*

Overall model: $R^2=0.35$; adjusted $R^2=0.30$; $F=7.39$; d.f.$=3,41$**.
* $p<0.05$.
** $p<0.01$.

Standardised HR-QoL: EORTC QLQ-C30

The amount of variation in each of the five QoL domains ranged from 32 to 57% (Table 5). The only non-psychological factor to contribute significantly to QoL was age, which partly explained Physical Functioning scores, in addition to Illness identity (IPQ-R) and beliefs about the Necessity of Treatment (BMQ) ($F=12.63$; d.f.$=3,49$; $p<0.01$). A large variation in global QoL/health (43%) was explained by levels of depression (HADS) and treatment concerns (BMQ) ($F=20.88$; d.f.$=2,50$; $p<0.01$). These correlations were inverse indicating that fewer concerns regarding treatment and lower levels of depression were associated with better global QoL.

Standardised HR-QoL: SF-12

The amount of variation explained in each of the 8 QoL domains ranged from 20 to 49% (Table 6). Depressive symptoms contributed significantly to five of the eight QoL domains. For example, variation in role physical ($F=14.44$; d.f.$=1,53$; $p<0.01$) and social functioning ($F=20.1$; d.f.$=1,51$; $p<0.01$) were explained by depression alone. Correlations were inverse, indicating that lower levels of depression were associated with better QoL.

About a third of the variation in general health ($F=11.32$; d.f.$=2,47$; $p<0.01$) could be explained by beliefs regarding the illness timeline (IPQ-R) and the maladaptive coping strategy of self-blame (Brief COPE). Stronger beliefs that the illness would last a long time and high levels of self-blame were associated with lower QoL on this domain. Similarly, with the domain of vitality, stronger beliefs that the illness would last a long time (timeline) and that the illness would come and go (timeline—cyclical) were associated with lower levels of vitality ($F=15.07$; d.f.$=2,50$; $p<0.05$).

Variation in role emotional (SF-12) was explained by depression and the maladaptive coping strategy of substance use (Brief COPE) ($F=19.55$; d.f.$=2,47$; $p<0.01$). Again, this correlation was inverse indicating that high levels of depression and high levels of substance use could explain low levels of Role Emotional QoL.

Sex, and treatment-related factors did not contribute significantly to any of the QoL domains in this sample.

Discussion

Although standardised HR-QoL measures are often used in patients with head and neck cancer within a clinical setting, it has been suggested that they fail to capture the individual's sense of 'quality of life'. This is because they do not focus on the individual's perception of QoL over and above standardised QoL related to pre-selected domains. In contrast, patient-generated outcome (individualised QoL) attempts to capture aspects of QoL that are most important to the individual at that particular time. Given the interest in the use of individualised measures in clinical trials[11,12] and in patients with

Table 5
Variation in HR-QoL (EORTC QLQ-C30) explained by independent variables

HR-QoL domain	Explanatory factor	β
Global QoL/health ($n=53$)	Depression	-3.73^{**}
	Treatment concerns (BMQ)	-1.33^{*}
Overall model: $R^2=0.46$; adjusted $R^2=0.43$; $F=20.88$; d.f. = 2,50**		
Physical functioning ($n=53$)	Age	0.02^{**}
	Illness identity (IPQ-R)	0.07^{**}
	Necessity of treatment (BMQ)	-0.07^{**}
Overall model: $R^2=0.44$; adj. $R^2=0.4$; $F=12.63$; d.f. = 3,49**		
Role functioning ($n=51$)	Depression	0.15^{**}
Overall model: $R^2=0.34$; adj. $R^2=0.32$; $F=24.99$; d.f. = 1,49**		
Emotional functioning ($n=53$)	Emotional representations (IPQ-R)	0.14^{**}
	Substance use (COPE)	0.13^{**}
Overall model: $R^2=0.58$; adj. $R^2=0.57$; $F=34.81$; d.f. = 2,50**		
Cognitive functioning ($n=53$)	Anxiety	0.07^{**}
	Illness identity (IPQ-R)	0.09^{**}
Overall model: $R^2=0.39$; adj. $R^2=0.36$; $F=15.85$; d.f. = 2,50**		
Social functioning ($n=51$)	Positive reframing (COPE)	0.18^{**}
	Timeline (IPQ-R)	0.14^{**}
Overall model: $R^2=0.35$; adj. $R^2=0.32$; $F=12.65$; d.f. = 2,48**		

* $p<0.05$.
** $p<0.01$.

Table 6
Variation in HR-QoL (SF-12v2) explained by independent variables

HR-QoL domain	Explanatory factor	β
Physical functioning ($n=52$)	Age	-0.96^{**}
	Depression	-2.79^{*}
Model: $R^2=0.26$; adj. $R^2=0.23$; $F=8.42$; d.f. = 2,49**		
Role physical ($n=55$)	Depression	-3.83^{**}
Model: $R^2=0.21$; adj. $R^2=0.20$; $F=14.44$; d.f. = 1,53**		
Bodily pain ($n=52$)	Depression	-4.16^{**}
	Illness identity (IPQ-R)	-2.52^{*}
Model: $R^2=0.35$; adj. $R^2=0.33$; $F=13.44$; d.f. = 2,49**		
General health ($n=50$)	Timeline (IPQ-R)	-5.25^{**}
	Self-blame (COPE)	-2.52^{**}
Model: $R^2=0.33$; adj. $R^2=0.30$; $F=11.32$; d.f. = 2,47**		
Vitality ($n=53$)	Timeline (IPQ-R)	-6.12^{**}
	Timeline cyclical (IPQ-R)	-2.38^{*}
Model: $R^2=0.38$; adj. $R^2=0.35$; $F=15.07$; d.f. = 2,50*		
Social functioning ($n=53$)	Depression	-4.4^{**}
Model: $R^2=0.28$; adj. $R^2=0.27$; $F=20.1$; d.f. = 1,51**		
Role emotional ($n=50$)	Depression	-4.89^{**}
	Substance use (COPE)	-4.82^{**}
Model: $R^2=0.45$; adj. $R^2=0.43$; $F=19.55$; d.f. = 2,47**		
Mental health ($n=50$)	Anxiety	-2.41^{**}
	Illness identity (IPQ-R)	-2.03^{**}
Model: $R^2=0.51$; adj. $R^2=0.49$; $F=24.29$; d.f. = 2,47**		

* $p<0.05$.
** $p<0.01$.

cancer in general,[13–15] the use of patient-reported outcomes could be beneficial in the area of head and neck cancer. It was previously not known how standardised QoL measures and individualised measures compared. In the present study we hypothesised that there would be no correlation between the measures because of their conceptual differences. The results of our study suggest that there is partial overlap between these measures and that the main overlap seems to exist between individualised QoL and domains assessing cognitive, emotional, and mental functioning. We therefore rejected the first null hypothesis.

In contrast to our results, the PGI has been related to physical aspects of HR-QoL in other groups of patients. For example, in a study of severely disabled patients with multiple sclerosis, individualised QoL (as assessed by the PGI) was related to a person's level of physical functioning, as opposed to a different patient-centred measure which seemed to be more related to feelings of health and vitality,[16] similar to the PGI in our study.

The PGI seems to be more responsive to change in health than the SF-36 and the EORTC-QLQ-C30 in other patients with cancer.[13] And may thus prove to be a more accurate tool for the assessment of the outcome of patients with cancer.

The self-regulation model[1–3] proposes that in response to a health threat, such as the diagnosis of cancer, people develop their own beliefs and emotional responses about their illness and treatment, which then influence the coping procedures that they adopt. These beliefs, emotional responses, and coping strategies then influence the outcome, which, in this study, were perceptions of QoL. As this is a constant process

of reappraisal, patients' beliefs and coping strategies may change over time. In the present study, a significant amount of variation in pre-treatment QoL (both individualised and standardised) could be explained by patients' perceptions of their illness and treatment, and by the coping strategy that they used. In particular patients' illness identity (the number of symptoms attributed to their head and neck cancer) and beliefs about the likely timeline (perceptions about the length of time the illness would last) explained a significant amount of variation in QoL (both individualised and HR-QoL). Treatment concerns and beliefs about the necessity for treatment were also important in this group of patients. This therefore led us to reject the other two null hypotheses. In the present study coping ability was related to QoL. In particular, the use of more adaptive strategies such as positive reframing was associated with better QoL, and maladaptive strategies such as substance use and self-blame were associated with a worse QoL. Previous research[17] has highlighted this relation between poor functioning and ineffective coping styles, such as helplessness and hopelessness, anxious preoccupation, and fatalism. List et al.[18] found that maladaptive coping strategies (cognitive escape-avoidance, sleeping more than usual, and behavioural escape avoidance, not seeking help or waiting before taking action) were related to poorer global QoL.

As reported by other authors,[19,20] depression explained a large amount of variation in HR-QoL. However, it is interesting to note that variation in patient-generated QoL was not explained by depressive symptoms. However, HR-QoL instruments include depressive symptoms, and it is not surprising that there is overlap with other scales that measure depression (for example, the HADS). The relation between physical symptoms, depression, and QoL is far from understood. Longitudinal research is needed to unravel these relations.

The main limitation of this study is its cross-sectional design. This means that no inferences can be made about which variables are exerting an influence on the others. The power of the study was low because of the few patients studied. This was overcome as much as possible by the selection of significant variables by univariate analysis before entering them into multivariate analyses. This reduced the number of variables entered into multivariate analyses. Despite these potential limitations, the findings are potentially relevant to clinical practice. If the PGI and the IPQ-R are used, clinicians may gain a better understanding of their patients' views about their illness and treatment, which would promote a better clinician–patient partnership.

Acknowledgements

CDL is supported by a grant from Guy's and St Thomas' Charitable Foundation (no: R020216). Thanks to all the patients and staff from Guy's and St Thomas' Hospitals, The Royal Sussex County Hospital, and The Royal Marsden Hospital who assisted with this project.

Appendix A

The European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (QLQ)-C30 is a well-known and validated questionnaire for self-completion. The instrument has 15 multi-item and single-item domains. For this study, only the five functional domains (physical, role, emotional, cognitive, and social) and global QoL/health domain were used in analyses. Higher scores for the functional and global domains of the core instrument signified better functioning.

The SF-12 is a multipurpose short-form consisting of 12 items, all selected from the SF-36 Health Survey.[21] Similar to the SF-36, the SF-12 is a generic measure and version 2 results in an eight-domain health profile (physical functioning, physical role, bodily pain, general health, vitality, social functioning, emotional role and mental health). Higher scores signified better functioning.

The Patient Generated Index is a global measure of QoL, based on the theoretical approach proposed by Calman[22] who defined QoL as 'the extent to which our hopes and ambitions are matched by experience'. The PGI is a three-stage self-completed measure. The first stage involves identifying a maximum of five areas of life that have been affected by the disease, plus 2 other boxes consisting of 'areas affected by other health problems' and 'all other non-health areas of life'. In the second stage, the respondent provides a rating of the degree to which reality meets expectations in each area listed (on a scale of 0 to 10, 0 indicating the area as the worst imaginable and 10 being exactly as wanted). In the third stage, the respondent is asked to imagine that any of these areas of life could be improved. The respondent is given 14 imaginary points to be spent on whatever areas are deemed to be the most important at that time. Finally an overall PGI score of between 0 and 10 is calculated, with higher scores indicating better individualised QoL.

The Illness Perception Questionnaire-Revised is an extensively used measure that assesses patient's beliefs and understanding of their illness in seven dimensions, and has confirmed validity and reliability across a range of illnesses.[8] It provides a quantitative assessment of the nature and strength of patients' beliefs about the following seven components: the nature of the patients illness 'identity', the number of symptoms they perceive to be related to their illness, how long the patient thinks their illness will last, and whether symptoms are sustained or cyclical; the perceived consequences of the illness; how much personal control the patient feels they have over their illness; whether patients have a coherent understanding of their illness; and finally the emotional picture the patient has of the illness. The higher the score on these dimensions the stronger the belief.

The Beliefs about Medicine Questionnaire (BMQ) was originally designed to assess patients' beliefs about medicines prescribed for personal use. It is a well-known and validated measure and has been used in a wide range of illnesses.[1] The BMQ-Specific was adapted to assess beliefs

about treatment in head and neck cancer and comprises two subscales assessing beliefs about the 'necessity' for treatment to health and 'concerns' about the possible side-effects and the disruptive effects of treatment. Higher scores reflect stronger beliefs about the necessity for treatment and stronger concerns.

The Hospital Anxiety and Depressioin Score (HADS) is a widely used and validated scale and was used to provide a brief measure of state anxiety and depression. Higher scores indicate greater anxiety or depression. Scores can range from 0 to 21 with scores of 11 or more indicating probable psychological morbidity.

The Brief COPE[10] is a validated multidimensional coping inventory, which was used in this study to assess situational coping. This short form version of the full COPE[23] assesses coping strategies on 14 conceptually different subscales—for example, coping by using self-distraction, using substances, using humour, positively reframing the situation, or self blame. Both adaptive and maladaptive coping strategies are therefore included.

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